UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNITED STATES OF AMERICA, Plaintiff, v. PHILIP MORRIS USA INC., f/k/a PHILIP MORRIS INC., *et al.*, Defendants.	Civil No. 99-CV-02496 (GK) Next scheduled court appearance: September 21, 2004

UNITED STATES' WRITTEN DIRECT EXAMINATION OF

DR. DAVID A. KESSLER

SUBMITTED PURSUANT TO ORDER #471

http://legacy.library.ucsf.edu/tid/qzq07a00/pdf
Guttata http://www.industrydocuments.ucsf.edu/docs/hqhl0001

Q: Please introduce yourself to the Court.

A: My name is David A. Kessler.

Q: Have you ever given testimony in Court before?

A: No, I have never testified in Court before. I have given deposition testimony before in this case and one other case involving Yale University.

Q: Are you testifying in Court today voluntarily?

A: Yes, I am testifying voluntarily.

Q: Were you paid for any of the time you spent preparing to testify in this case?

A: No.

Q: Why did you agree to testify in this case?

A: I was asked to testify by the Department of Justice. My understanding is that this case involves the tobacco industry and their conduct in a range of issues. When I was Commissioner of FDA, I supervised an investigation of the tobacco industry. The findings of the FDA, and the results of our investigation, may be significant for this Court. That is why I agreed to testify.

Q: Between 1990 and 1997, you served as the Commissioner of the United States Food and Drug Administration, correct?

A: Yes, that is correct. I began in late 1990 and stepped down in early 1997.

Q: When you held the position of Commissioner of the Food and Drug Administration, what did it entail?

A: The Commissioner is responsible for all the activities of the FDA. Unlike some other federal agencies, there is only one Commissioner. The Commissioner is responsible for implementing the Federal Food, Drug and Cosmetic Act, as amended, and numerous public health service acts including one for biological products, one for radiation control, and one for quarantine and inspection. There are a number of other federal statutes such as the Federal Anti-Tampering Act, the Orphan Drug Act and the Pesticide Monitoring Act. The FDA is involved in regulating and assuring the safety of numerous consumer products. Approximately 25 percent of

http://legacy.library.ucsf.edu/tid/qzq07a00/pdf
Digitized by the Internet Archive in 2014 http://www.industrydocuments.ucsf.edu/docs/hqhl0001

every consumer dollar is regulated by the FDA. The type and range of products within the FDA's jurisdiction is considerable.

Q: Please describe generally the investigation of the tobacco industry conducted by the Food and Drug Administration while you were Commissioner.

A: The investigation focused on the question of whether nicotine in cigarettes was a drug under the jurisdiction of the Federal Food Drug and Cosmetic Act, and also involved an investigation into the marketing practices of the tobacco industry. The investigation focused on the knowledge, research, and actions of cigarette manufacturers.

Q: Explain the relationship, if any, between the intent of the cigarette manufacturers regarding nicotine in cigarettes and the FDA's ability to assert jurisdiction over cigarettes.

A: This is a key point. The question we were asking was whether nicotine in cigarettes was a drug under the Federal Food Drug and Cosmetic Act. The relevant portion of the statutory definition of a drug is "an article (except for food) intended to affect the structure or any function of the body." That is Section 201(g)(1)(C). So the question we had to answer was not only whether nicotine affects the structure or any function of the body, but whether the cigarette companies "intended" nicotine in cigarettes to affect the structure or any function of the body. So we had to gather evidence regarding the question of intent.

Q: Are you familiar with who the defendants are in this case?

A: I am.

Q: Who are they?

A: I believe they include Philip Morris USA, Altria, R.J. Reynolds, Lorillard, Brown & Williamson, British American Tobacco, American Tobacco, Liggett, Council for Tobacco Research, and the Tobacco Institute. I recognize that there have been changes in some of the names of these entities over the years.

Q: The FDA review included evidence relating to each of the defendants in this case that you have named, correct?

http://legacy.library.ucsf.edu/tid/qzq07a00/pdf
Digitized by the Industry Documents Library
http://www.industrydocuments.ucsf.edu/docs/hqhl0001

A: I believe the answer is yes. There may be distinctions in corporate names that I am not taking into full account or do not remember. For example, I know we reviewed documents of Philip Morris USA. I don't recall specifically whether we reviewed documents of Philip Morris Companies. Furthermore, we did not review documents for Altria; we did review documents for Philip Morris.

Q: And this extensive review included numerous documents created by or for the cigarette industry, including the defendants in this case, correct?

A: Yes, that is correct.

Q: As a result of the evidence the FDA reviewed during the investigation, did the FDA promulgate a Rule asserting jurisdiction over cigarettes?

A: As a result of the evidence we reviewed, we promulgated regulations restricting the sale and the distribution of cigarettes to protect children and adolescents. The issues involving jurisdiction were discussed in that Rule and in separate documents that accompanied that Rule.

Q: Generally, what was the basis for the Food and Drug Administration's assertion of jurisdiction?

A: FDA's assertion of jurisdiction was based on the findings that nicotine in cigarettes is a drug and that these products are nicotine delivery devices under the Federal Food Drug and Cosmetic Act. It included the finding that the cigarette manufacturers intended nicotine in cigarettes to affect the structure and function of the body within the meaning of the Act.

Q: Describe for the Court the nature of your participation in the investigation.

A: I think it is fair to say that I led the team that conducted the investigation. It was a very talented and dedicated team. I think it is also accurate to say that I was a member of the team. At times, I was called on by my colleagues to assist them because of my scientific or medical background. I was extensively involved in the investigation.

Q: Dr. Kessler, before I ask you more detailed questions about the FDA's investigation of cigarettes, I want to ask you some questions about your background. Please describe

http://legacy.library.ucsf.edu/tid/qzq07a00/pdf Document hosted at industrydocuments.ucsf.edu/docs/hqhl0001

your general education, including your medical and legal background.

A: I am a graduate of Amherst College. I received my medical degree from the Harvard Medical School and my law degree from the University of Chicago Law School.

Q: Did you complete your medical degree during some of the same time periods during which you completed your studies to be an attorney?

A: Yes. The University of Chicago Law School allowed me to complete my third year at the Harvard Law School. I did complete my third year of law school and third year of medical school at the same time.

Q: Have you ever taught law?

A: Yes, I taught at Columbia University Law School.

Q: Following graduation from medical school, did you complete a medical internship and a medical residency?

A: Yes, in pediatrics.

Q: Describe your internship and residency for the Court.

A: I completed my internship and residency in pediatrics at Johns Hopkins.

Q: Were you responsible for patient care during your residency?

A: Yes.

Q: And what experience, if any, did you gain in that internship and residency relating to cancer?

A: Because of my interest in pediatric oncology, I spent a considerable part of my internship and residency taking care of children with cancer.

Q: Please explain what experience, if any, you have in the area of cancer biology.

A: My undergraduate thesis – work that I did over a two year period – focused on a tumor that was associated with a herpes-like virus. I worked for a number of summers in the division of drug resistance at Memorial Sloan Kettering. I spent close to a year in medical school working in the laboratory of Dr. Judah Folkman on tumors and their blood vessels.

http://legacy.library.ucsf.edu/tid/qzq07a00/pdf Document hosted at industrydocuments.ucsf.edu/docs/hqhl0001

Q: What is cancer biology?

A: It is the study of the molecular and cellular basis of cancer. It focuses on why cancer develops and how it progresses.

Q: Are you a pediatrician?

A: I am.

Q: What is a pediatrician?

A: A physician who focuses on child and adolescent health.

Q: How long have you been a pediatrician?

A: More than 20 years.

Q: Are you currently a professor of pediatrics?

A: I am.

Q: What other academic positions, if any, have you held in the field of pediatrics?

A: I was professor of pediatrics from 1997-2003 at the Yale University School of Medicine. During the 1980s I held academic appointments in pediatrics at the Albert Einstein College of Medicine. I served as an attending pediatrician in the emergency rooms of some of New York City's public hospitals, specifically the Bronx Municipal Hospital Center and the North Central Bronx Hospital.

Q: Have you authored any books?

A: I have.

Q: How many books have you authored?

A: I have authored one book and edited another.

Q: What was your book about?

A: The book that I authored dealt primarily with my experiences at FDA and especially our investigation in tobacco. The book that I edited dealt with long-term care of the elderly.

Q: What articles, if any, relating to tobacco or cigarettes have you written that were published?

http://legacy.library.ucsf.edu/tid/qzq07a00/pdf
Digitized by the Industry Documents Library
http://www.industrydocuments.ucsf.edu/docs/hqhl0001

A: I have published articles in the New England Journal of Medicine, the Journal of the American Medical Association, the Journal of Pediatrics, and Pediatrics on cigarettes and tobacco.

Q: Have you received any honorary degrees?

A: I have.

Q: How many?

A: More than a dozen.

Q: Please describe these degrees and the dates on which you received them.

A: I have received honorary degrees from the college I attended, other liberal arts colleges, schools of law, schools of medicine, schools of pharmacy, as well as universities. One honorary degree that is particularly memorable is an honorary doctor of Public Service degree from the University of Louisville in Louisville, Kentucky in 2002.

Q: Which of the honorary degrees you have received, if any, relate specifically to the work that you did as the Commissioner of the Food and Drug Administration?

A: Honorary degrees are usually given for the totality of one's work. Many of the citations that accompany the honorary degrees specifically reference the work on tobacco.

Q: You mentioned the honorary degree you received from the University of Louisville in Louisville, Kentucky. Please explain any special significance this honorary degree has to you.

A: During the mid-1990s when we were conducting our investigation of tobacco, I was invited to give a lecture at one of the major public universities in one of the tobacco-growing states. I understand an official at the University at the time received a call from a state legislator saying that, if I came to give the lecture, that legislator would try to cut the University's budget. So, years later, when I was officially invited to get an honorary degree from a public university in a tobacco-growing state, it was memorable.

Q: Now I would like to turn to your employment. Where do you work?

http://legacy.library.ucsf.edu/tid/qzq07a00/pdf Document hosted at industrydocuments.ucsf.edu/docs/hqhl0001

A: I work at the University of California, San Francisco, which is the health science campus for the University of California system. I am also currently Chairman of the Board of the Elizabeth Glaser Pediatric AIDS Foundation. The latter is a volunteer position. I also serve on other boards.

Q: Describe your responsibilities and the work you at the University of California, San Francisco.

A: I am Dean of the School of Medicine and Vice Chancellor of Medical Affairs. I am a professor of pediatrics and a professor of epidemiology and biostatistics.

Q: How long have you held your position at the University of California, San Francisco?

A: Since last September.

Q: What subjects, if any, do you teach?

A: I teach in a number of different areas, including medicine, pediatrics, epidemiology, public health, public policy and law.

Q: Describe the teaching positions, if any, that you held before becoming Dean and Vice Chancellor of the Medical School of the University of California, San Francisco.

A: I was Professor of Pediatrics, Internal Medicine and Public Health at Yale University. As I mentioned earlier, I taught at Columbia University School of Law. I have served as Attending Pediatrician for many years, and have taught medical students and residents. I was a Teaching Assistant in Chemistry and Biology during my undergraduate years.

Q: Where were you employed before you accepted your current position at the University of California, San Francisco?

A: I was employed at Yale University.

Q: During what time period?

A: From 1997 to 2003.

Q: Describe your employment at Yale University School of Medicine.

http://legacy.library.ucsf.edu/tid/qzq07a00/pdf Document hosted at industrydocuments.ucsf.edu/docs/hqhl0001

A: I was Dean of Yale University School of Medicine.

Q: What job did you hold before you became Dean of the Yale University School of Medicine?

A: I was Commissioner of the United States Food and Drug Administration.

Q: Describe the work experience you had when you came to the position of Commissioner of the Food and Drug Administration?

A: I had taught Food and Drug law and authored a number of papers in both medical and legal literature on issues involving the federal regulation of food, drugs, and medical devices. I also had experience on the Senate Labor and Human Resource Committee, which had jurisdiction over the FDA. I worked on FDA issues when I was with the Senate Committee staff.

Q: During what time period did you serve as the Commissioner of the Food and Drug Administration?

A: 1990 to 1997.

Q: How were you selected to be the Commissioner of the Food and Drug Administration?

A: Usually the selection is by the Secretary of Health and Human Services and the White House. This was somewhat different, in that the Administration put together an independent search committee that made recommendations to the Secretary and the White House. The reason for this search committee, I believe, was that the agency was coming out of a difficult period of time after a scandal in the generic drug division. My understanding is that the search committee recommended my name. I was then interviewed by Secretary Sullivan and people in the Executive Office of the President. I was the first Commissioner to be confirmed by the United States Senate.

Q: What was Secretary Sullivan's specific job title?

A: He was Secretary of Health and Human Services.

Q: What went through your mind when you learned that you had been appointed

http://legacy.library.ucsf.edu/tid/qzq07a00/pdf
Digitized by the Industry Documents Library
http://www.industrydocuments.ucsf.edu/docs/hqhl0001

Commissioner of the Food and Drug Administration?

A: I have to think back. I grew up as part of a generation that believed in public service. I was a kid when Kennedy was president. Public service was a part of us. I was obviously excited.

Q: When you learned that you had been appointed Commissioner of the Food and Drug Administration, did you have any thoughts that your duties as Commissioner of the Food and Drug Administration might relate to tobacco or the tobacco industry?

A: Absolutely not. It did not cross my mind at all.

Q: Who appointed you as Commissioner of the Food and Drug Administration?

A: President George Herbert Walker Bush.

Q: And then did you go through a confirmation process in the U.S. Senate?

A: Yes I did.

Q: What did the confirmation process entail?

A: Full field background check by the FBI, interviews by Congressional staff, meetings with members of the Senate Committee and other Senators, completion of numerous forms, and answering in writing questions about the FDA.

Q: Was there a hearing before you were confirmed?

A: No. The Committee decided to hold the hearing after I was confirmed.

Q: By what margin were you confirmed?

A: By unanimous consent.

Q: How long did your confirmation process take?

A: About eight days.

Q: How does that time period compare to the customary time for confirmation to be a head of a United States Governmental Agency?

A: It is significantly shorter.

Q: After being appointed by President Bush and confirmed as Commissioner of the

http://legacy.library.ucsf.edu/tid/qzq07a00/pdf Document hosted at industrydocuments.ucsf.edu/docs/hqhl0001

FDA, did you continue to serve as Commissioner of the Food and Drug Administration during the Administration of President Clinton?

A: Yes.

Q: What did you want to accomplish when you took the position of Commissioner of the Food and Drug Administration?

A: There were several things I was focused on. First, as a physician coming from the Bronx, and having been involved with AIDS, and with only one AIDS drug available at the time, I was intent on finding other drugs that could be used in the treatment of that epidemic, as well as other serious and life-threatening diseases. Second, I was interested in labeling foods for nutritional content – the nutritional fact label that is now on packaged foods. And third, I was interested in enforcing the laws under FDA's jurisdiction.

Q: Did you arrive at the position of Commissioner of the FDA with plans to take any actions relating to tobacco or cigarettes?

A: No. As I said earlier, it never crossed my mind.

Q: Describe how the issue of regulation of tobacco first arose during your service as FDA Commissioner?

A: A person who worked at the Agency raised the issue with me several months after I arrived at the agency; I don't remember the exact date.

Q: How did you respond?

A: I looked at him as if he were crazy.

Q: What happened next leading to your looking into regulation of tobacco?

A: After he raised the issue several times, I finally agreed that we could have a briefing on the subject, which involved more than a dozen officials from the Agency with various backgrounds.

Q: Did you have any reservations about examining the tobacco industry?

A: I am not sure that I did, but some of my colleagues certainly at that briefing articulated

http://legacy.library.ucsf.edu/tid/qzq07a00/pdf
Document hosted at industrydocuments.ucsf.edu/docs/hqhl0001

their reservations about examining the tobacco industry.

Q: Describe those reservations.

A: Simply put, some viewed it as a fool's errand. There were concerns the industry would come after the Agency, that our budget would be at risk, that it would consume all our energy and time. Some viewed it as political suicide. Others at that briefing that day were supportive of looking at the question of whether FDA should regulate tobacco.

Q: What effect, if any, did this briefing have on your opinions?

A: I remember giving a rather neutral response at the end of the briefing. Something like "We'll get to this," but there were other issues that I wanted to focus on. I did agree to have a small working group look into the issue.

Q: Did you decide, notwithstanding those reservations, to institute an investigation of the tobacco industry by the Food and Drug Administration?

A: Yes, but it would be several years before we began the more formal investigation.

Q: Why?

A: Some time after the briefing, I agreed to set up a working group that could look into the issue. Only after the working group had gathered some preliminary evidence that, in fact, tobacco companies might know that nicotine in cigarettes was a drug, did I begin to focus my attention on tobacco.

Q: Of what types of tobacco products did the Food and Drug Administration conduct an in-depth investigation?

A: Cigarettes and smokeless tobacco.

Q: Although the Food and Drug Administration investigated both cigarettes and smokeless tobacco, this lawsuit is about cigarettes, so my questions to you will focus on cigarettes, as opposed to smokeless tobacco. What was the question that the Food and Drug Administration endeavored to answer during the early stages of the investigation of the cigarette industry?

http://legacy.library.ucsf.edu/tid/qzq07a00/pdf
Digitized by the Industry Documents Library
http://www.industrydocuments.ucsf.edu/docs/hqhl0001

A: The question the investigation was aimed at was whether nicotine in cigarettes was a drug under the Act.

Q: What did the investigation entail?

A: We wanted to understand what the industry knew about nicotine and what it did with nicotine in cigarettes.

Q: What was the approach used by the Food and Drug Administration in deciding what evidence to look at during the investigation?

A: Gary Light and Tom Doyle, investigators on the team, told me early on that it was important that we look broadly and not prejudge where evidence might exist. Both Light and Doyle were experienced investigators with the Office of Criminal Investigations at FDA. Mr. Light was previously with Army Criminal Investigative Division. Mr. Doyle was with the Secret Service.

Q: What collections of documents, if any, can you recall that the Food and Drug Administration reviewed in examining what the cigarette manufacturers intended with regard to the nicotine in cigarettes?

A: I remember we reviewed documents that were in the public record; patents; documents from the collection of John Hill, a co-founder of the public relations firm Hill and Knowlton, at the Wisconsin Historical Society; documents from the archives of Clarence Cook Little, the first director of the Tobacco Industry Research Council, at Jackson Laboratory; documents from a number of Court cases relating to cigarettes, including Cipollone, Haines, Mangini, and others; documents from the archives of an organization called "Docs," standing for Doctors Ought to Care; what was referred to as the Merrill Williams documents; documents from other federal agencies including the Federal Trade Commission; archives from the Office of the Surgeon General and the Surgeon General's Reports; Customs records; documents submitted to the FDA docket; documents that were given to the Agency, including documents that were given to us by Congressional staff; documents in the archives of Richard Pollay, a professor who studied the

http://legacy.library.ucsf.edu/tid/qzq07a00/pdf
Digitized by the Legacy Industry Documents Library. http://www.industrydocuments.ucsf.edu/docs/hqhl0001

history of cigarette marketing and advertising at the University of British Columbia; documents from the National Clearinghouse on Tobacco and Health in Canada; documents from the archives of S.J. Green, who was a scientist and on the board of British American Tobacco; Institute of Medicine documents; numerous books, journals, articles, and tobacco publications; Mealey's Litigation Report: Tobacco; and Northeastern University Tobacco Litigation Project documents. I do not mean for this list to be exclusive.

Q: What measures, if any, did the FDA take to ensure the validity of the results of its investigation?

A: While we interviewed many people for the investigation, including certain confidential informants, we tried to document all our findings. Furthermore, we published our findings in the Federal Register and provided an opportunity for broad public comment.

Q: How were decisions made as to how to proceed with the investigation?

A: We would make the decisions as a team, or in some cases I would make the decisions with individual members of the team.

Q: How long did the investigation take?

A: The investigation took place over several years. There was an informal phase through 1992 and 1993. The bulk of the investigation took place in 1994 and 1995.

Q: As FDA Commissioner, did you use your knowledge of pediatrics during the course of the FDA investigation of the tobacco industry or the promulgation of the regulation?

A: Yes. It was especially important during the second phase of our investigation into the marketing practices of the industry. My pediatrics training was useful in understanding why children smoke.

Q: As FDA Commissioner, did you use any other medical and scientific knowledge during the course of the investigation of the tobacco industry or the promulgation of the regulation?

A: Yes, my knowledge of chemistry, biology, pharmacology – the study of drugs,

http://legacy.library.ucsf.edu/tid/qzq07a00/pdf http://www.industrydocuments.ucsf.edu/docs/hqhl0001

epidemiology – the study of diseases in populations, cancer biology, and neuroscience – especially drug effects on the brain, was important.

Q: How?

A: The industry had conducted significant scientific research on nicotine and its effects. There were times where I was called upon to explain what this research meant to members of the FDA team. Similarly, I was able to have discussions at a scientific level with other members of the FDA team, interviewees who were themselves scientists, and outside experts.

Q: Did you have any preconceived notions of any kind relating to the Food and Drug Administration investigation of the tobacco industry when it began?

A: When we started the investigation I had little understanding of where it might lead or what we might find. I certainly did not have any preconceived notions regarding whether or not FDA would assert jurisdiction.

Q: Describe how the FDA began to go about examining the cigarette industry and your role in that investigation.

A: Early on, the working group did some preliminary investigation into the question of whether nicotine in cigarettes was a drug under the Act. Only after I saw preliminary evidence, and was asked to testify before Congress, did we more formally expand the investigation.

Q: What publicly available documents did FDA look at in the beginning of the FDA investigation of the cigarette industry?

A: In the beginning, we focused extensively on patents filed by the cigarette manufacturers. The patents were our first window into the role of nicotine and cigarette manufacturing and design.

Q: Describe what the early review of patents uncovered.

A: We saw patents that were aimed at increasing nicotine content in cigarettes by adding nicotine to filters and paper wrappers on cigarettes. We also saw patents to increase the nicotine content of cigarettes by adding nicotine to the tobacco rod itself. There was a patent whose

http://legacy.library.ucsf.edu/tid/qzq07a00/pdf
Digitized by the Industry Documents Library http://www.industrydocuments.ucsf.edu/docs/hqhl0001

stated purpose was to make high nicotine less harsh by adding an organic acid to tobacco. I noted this, because it was a patent to mask the harshness of nicotine, in contrast to the assertions by the tobacco industry that nicotine was in cigarettes for taste and flavor. We also saw patents for the development of new nicotine-like molecules that the tobacco companies had synthetically developed through chemistry. I noted that, in two of these patents for these nicotine-like molecules, the company stated that the molecules had tranquilizing effects, in contrast to their assertions that nicotine was simply for pleasure or taste. It would take several months into our investigation before we fully understood the significance of these nicotine-like molecules.

Q: What experts did FDA deal with in the early stages of its investigation?

A: These included, but were not limited to, Jack Henningfield, of the National Institute on Drug Abuse, Neal Benowitz, a pharmacologist at the University of California, San Francisco, and colleagues from sister agencies, including the Federal Trade Commission, the Bureau of Alcohol Tobacco and Firearms, and the National Institutes of Health.

Q: Describe the work they did.

A: They were experts on drug use, pharmacology, tobacco and patents. I, and/or members of the tobacco team, met with these individuals in an attempt to understand the relevant issues. Dr. Henningfield had worked in the area of addiction and pharmacology; Dr. Benowitz worked in the area of pharmacology; and our colleagues from the other agencies explained their involvement with tobacco.

Q: Did you receive petitions asking FDA to regulate cigarettes as a drug?

A: Yes; there were several petitions seeking to regulate certain types of cigarettes as a drug.

Q: How did the FDA respond?

A: We responded generally in a letter dated February 25, 1994, and signed by me.

Q: How did the United States' Congress respond?

A: Certain members of Congress that I spoke with days after the letter asked us to testify on whether the companies intended nicotine's effect as a drug.

http://legacy.library.ucsf.edu/tid/qzq07a00/pdf
Digitized by the Legacy Industry Documents Library. http://www.industrydocuments.ucsf.edu/docs/hqhl0001

Q: What actions, if any, did the FDA take in response to the call for hearings by the United States Congress?

A: I remember after that conversation with those members of Congress that I called my office and gave my assistant the names of individuals I wanted to meet with when I got back to the office. That meeting that afternoon really was the starting point for the more formal investigation. It built upon the earlier work of the working group.

Q: On what date did the FDA investigation formally begin?

A: On February 28, 1994.

Q: Did the FDA ask the members of the cigarette industry who are defendants in this case what they intended regarding the nicotine in cigarettes?

A: The FDA representatives met with company officials at Philip Morris, Brown & Williamson, and R.J. Reynolds. Over the course of our investigation there were a number of exchanges regarding what the companies intended regarding nicotine in cigarettes. Each of the companies formally submitted comments about their intent regarding nicotine in cigarettes. They also submitted joint comments.

Q: What did the representatives of these companies say, if anything, relating to the nicotine in the cigarettes they sold?

A: The cigarette manufacturers denied that nicotine was addictive, denied that they manipulated the level of nicotine in cigarettes, stated that nicotine was in cigarettes for flavor and taste, denied that they intended nicotine's drug effects, and denied that consumers were misled by the published nicotine deliveries, as measured by the FTC Method.

Q: Why, if at all, was the issue of manipulation of nicotine by the cigarette industry relevant to the FDA investigation?

A: If the companies were manipulating nicotine, that was relevant to the question of their intent. If they were manipulating the levels of nicotine, they had to be doing it for a reason. The companies vociferously denied manipulating nicotine levels. Nicotine, they argued, was found

http://legacy.library.ucsf.edu/tid/qzq07a00/pdf Document hosted at industrydocuments.ucsf.edu/docs/hqhl0001

naturally in tobacco and was in cigarettes for its taste and flavor. They also asserted that they did not intend nicotine's drug effects.

Q: Who, as representatives of one or more Defendants, responded to the FDA's inquiry as to what the cigarette industry intended concerning the nicotine in cigarettes?

A: Responses to FDA's inquiry included comments by numerous tobacco company representatives during FDA visits to the companies, public statements by company officials regarding FDA's inquiry, comments submitted to the FDA docket on each company's behalf, and testimony of company officials before the Congress regarding FDA's inquiry.

Q: Who are William Campbell and Alexander Spears?

A: I believe Mr. Campbell had a title like CEO of Philip Morris, and Dr. Spears had a title like Vice Chairman and Chief Operating Officer at Lorillard.

Q: Did Mr. Campbell and Dr. Spears, as representatives of their respective companies, address the issue of the intent of the cigarette industry concerning nicotine?

A. Yes.

Q: Where did Mr. Campbell make Philip Morris's views known?

A: In testimony before Congress.

Q: Where did Dr. Spears make Lorillard's views known?

A: In testimony before Congress.

Q: When did Mr. Campbell testify?

A: April 14, 1994.

Q: Please review U.S. Exhibit 21,990. What is this exhibit?

A: This is a transcript of the hearing of the House Subcommittee on Health and the Environment on the subject of nicotine in cigarettes.

Q: Does U.S. Exhibit 21,990 contain the testimony by Mr. Campbell that you referred to?

A: Yes.

http://legacy.library.ucsf.edu/tid/qzq07a00/pdf
Document hosted at industrydocuments.ucsf.edu/docs/hqhl0001

Q: For purposes of the FDA investigation, what testimony by Mr. Campbell was considered to be most pertinent to the issues before the FDA?

A: Mr. Campbell stated that Philip Morris did not manipulate the level of nicotine in their products, he further stated that nicotine contributes to the taste of cigarettes and the pleasures of smoking. The presence of nicotine, he stated, does not make cigarettes a drug or smoking an addiction.

Q: When did Dr. Spears testify before the U.S. Congress on this issue?

A: He testified on both March 25 and April 14, 1994.

Q: What testimony, if any, by Dr. Spears did the FDA consider most significant on the issue of nicotine manipulation?

A: Dr. Spears, in his testimony before Congress, stated that the "easy proof" that no nicotine manipulation has occurred could be found in the FTC tar and nicotine data from the 1950s to 1990s. Nicotine levels, he insisted, follow the tar levels. Spears stated that both tar and nicotine on a sales weighted basis decreased in parallel fashion and by the same amount.

Q: What did the FDA do, if anything, to verify the claims by Dr. Spears that nicotine levels had fallen historically?

A: We formally requested from our colleagues at the Federal Trade Commission data on the levels of nicotine and tar in cigarettes.

Q: Describe the information the Food and Drug Administration obtained from the Federal Trade Commission.

A: What we found was that since 1982, which was the earliest year for which the computed database was available, the sales weighted levels of nicotine in cigarettes increased, while the tar levels decreased.

Q: What did this information indicate?

A: It suggested that the companies might be manipulating the nicotine levels in cigarettes.

Q: Dr. Kessler, please review Demonstrative Exhibit DK001. What is this exhibit?

http://legacy.library.ucsf.edu/tid/qzq07a00/pdf
Document hosted at industrydocuments.ucsf.edu/docs/hqhl0001

A: This is a replication of a graph that appears on page A-228, which is the appendix to the Jurisdictional Document that accompanies the FDA Proposed Rule. It also appears on page 41,728 of the August 11, 1995 Federal Register, which contains FDA's Jurisdictional Determination accompanying the Proposed Rule.

Q: On what is the data in DK001 based?

A: It was based on data submitted to FDA by the Federal Trade Commission.

Q: Please explain the significance of the data depicted in Demonstrative Exhibit DK001, if any, to the FDA investigation that you led as FDA Commissioner.

A: It depicts that there is an apparent increase in sales-weighted FTC nicotine delivery ratings for all cigarettes since 1982, while there is no such increase in tar levels. 1982 was the earliest year for which the FTC had a computer database available. If, as the industry stated, nicotine follows tar, I would not have expected nicotine to increase and tar to decrease as I saw when the data was plotted.

Q: What, if anything, did the information from the Federal Trade Commission indicate with regard to the nicotine in low tar cigarettes?

A: There were percent increases in the nicotine levels in the lowest tar category of cigarettes. That raised the question that the companies might be manipulating the level of nicotine in their cigarettes.

Q: Was this news to the FTC?

A: Yes; even though it was their data, they had never looked for increases in nicotine to tar ratios in lighter cigarettes.

Q: Please explain the significance of the FDA discovery that nicotine levels were rising and tar levels were decreasing in the FTC numbers.

A: As I would later come to understand, the tobacco industry, for the last several decades, was confronted with a problem. They understood that smokers smoke primarily for nicotine. They also wanted to sell "light"cigarettes.

http://legacy.library.ucsf.edu/tid/qzq07a00/pdf Document hosted at industrydocuments.ucsf.edu/docs/hqhl0001

The industry used a number of different techniques to produce "light" cigarettes. Smokers wanted to reduce the amount of chemicals that they inhaled when they smoked. The problem was that, as the industry made cigarettes "lighter," they would also be reducing the amount of nicotine that a smoker received. The industry understood that, if smokers did not receive an adequate amount of nicotine, they would either switch cigarettes or quit smoking altogether. So what the industry was faced with was the need in "light" cigarettes to provide smokers within adequate level of nicotine.

The significance of the industry's attempt to provide smokers with an adequate level of nicotine–an adequate "dose" of nicotine–went to the question of whether the industry knew nicotine was a drug. If the goal of the industry was to provide consumers with an adequate dose of nicotine, then it would appear the industry understood that nicotine was a drug.

The Court should understand that the issue of nicotine manipulation was relevant to the FDA, not because we took any position on whether nicotine manipulation was a good or bad thing, but because it went to the question of whether the industry understood that nicotine was a drug.

Q: What, if anything, did the FDA do to test cigarettes sold in the United States?

A: Our drug laboratory in St. Louis tested cigarettes; the tests included, among other analyses, measuring the level of nicotine in specific brands of cigarettes.

Q: Describe the Food and Drug Administration Drug Labs in St. Louis, Missouri.

A: The laboratory did sophisticated chemical analyses relating to the potency and purity of drugs.

Q: Describe the most significant research and testing that the St. Louis Laboratory performed for the Food and Drug Administration investigation of the cigarette industry?

A: There were two significant findings. First, the St. Louis Laboratory compared the content uniformity in either tablets or capsules of known pharmaceuticals to the content uniformity nicotine in cigarettes. What was striking was how uniform the nicotine content was in cigarettes.

http://legacy.library.ucsf.edu/tid/qzq07a00/pdf
Digitized by http://www.industrydocuments.ucsf.edu/docs/hqhl0001

The level of variability of nicotine from cigarette to cigarette to cigarette was about as tightly controlled as the level of variability of a drug from tablet to tablet. In fact, the St. Louis Laboratory demonstrated that the precision of nicotine controlled in cigarettes met the drug standards set by the U.S. Pharmacopeia-the national organization that sets drug quality standards. That level of precision and control has suggested that the manufacturers were exercising tight control on the amount of nicotine in cigarettes.

Second, the St. Louis Laboratory measured the percent concentration of nicotine in different cigarettes. What was striking was that the nicotine concentration in the Merit brand family was 1.46 percent nicotine concentration (mg/grams) for Merit regular cigarettes, 1.67 percent nicotine concentration for Merit light cigarettes and 1.99 percent nicotine concentration for the lightest Merit brand, Ultima. Thus, the lightest variety had the highest concentration of nicotine.

Q: Dr. Kessler, please review Demonstrative Exhibit DK002. What is this exhibit?

A: It is a diagram which contains the results of the relative nicotine concentrations in the regular, low tar, and ultra-low tar versions of Merit cigarettes.

Q: What is the source of the data in DK002?

A: That data is found in the August 28, 1996 Federal Register, page 44,956, and also on page A-224 of the Appendix to the Jurisdictional Document that accompanies the FDA Proposed Rule.

Q: What, if anything, did this data indicate to the FDA during the investigation of the cigarette industry while you were FDA Commissioner?

A: This data shows that nicotine concentrations in this brand variety were highest in the ultra-low-tar–the "lightest" versions of Merit cigarettes.

Q: Why was the research and testing by the St. Louis Laboratory significant to the FDA investigation of the industry?

A: The fact that "lighter" cigarettes had higher concentrations of nicotine, and there was

http://legacy.library.ucsf.edu/tid/qzq07a00/pdf Document hosted at industrydocuments.ucsf.edu/docs/hqhl0001

remarkable consistency in nicotine concentration in cigarettes within each brand category, could not occur by accident. The manufacturer had to be controlling and manipulating the level of nicotine is these brands.

Furthermore, the fact that the lightest cigarettes had the highest level of nicotine suggested that the manufacturer intended to provide an adequate level of nicotine to those people who smoked that brand.

Q: Did the FDA ever conclude how the cigarette industry was able to put the highest concentration of nicotine in the lightest cigarettes?

A: Yes, different types of tobacco contained different levels of nicotine. Furthermore, tobacco leaves higher up on the plant–higher stalk positions–also had higher nicotine concentrations. By choosing higher nicotine tobacco leaves, the companies were able to achieve the desired levels of nicotine. This technique was referred to in the industry as "blending."

Q: Describe the evidence that supported this conclusion by the FDA.

A: Members of the FDA team met with company officials. The first visit was with Philip Morris representatives at their plant in Richmond, Virginia. During that visit Philip Morris representatives insisted that Philip Morris did not manipulate the level of nicotine in cigarettes and that there was an inviolate ratio of tar to nicotine–15-to-1. As tar goes down so does nicotine, the company asserted. That evening back in the hotel room, several FDA officials were reviewing tar to nicotine ratios in the company's cigarettes. Something did not seem right to the FDA officials since, in one of Philip Morris' lighter brands of cigarettes, the ratio was closer to 10-to-1. FDA officials the next day requested formulas for these cigarettes. The company officials changed their position and acknowledged that the tar to nicotine ratio was not actually immutable. It became clear to FDA officials during that visit that the higher nicotine concentrations in lighter cigarettes achieved by "blending" different types of tobacco leaves. The industry later–the Tobacco Institute and the five major cigarette manufacturers–confirmed in jointly submitted documents to the agency that leaf blending was one of the primary means the

http://legacy.library.ucsf.edu/tid/qzq07a00/pdf Document hosted at industrydocuments.ucsf.edu/docs/hqhl0001

industry uses to control nicotine levels in cigarettes.

Q: While FDA Commissioner, did you testify before the United States Congress on the issue of cigarettes?

A: Yes.

Q: How many times did you testify before Congress on the issue of cigarettes as the FDA Commissioner?

A: I testified twice in 1994 during the FDA investigation specifically on tobacco. I am sure there were other hearings where the issue of tobacco was raised while I was testifying.

Q: When was the first time you testified before Congress on this issue?

A: March 25, 1994.

Q: Describe the subject matter of your testimony.

A: I testified that accumulating evidence suggested that cigarette manufacturers may be controlling smokers' choice by controlling the levels of nicotine in the cigarettes in a manner that creates and sustains addiction in a majority of smokers. I reviewed the industry's patents. I believe I discussed similarities between the tobacco industry and the pharmaceutical industry in trying to control levels of physiologically active substances, be they drugs or nicotine.

I also discussed the fact that we were concerned, not only with the control over nicotine levels by the tobacco industry, but also that the problems associated with nicotine were aggravated by limitations in the consumers ability to reduce their exposure to nicotine in "light" cigarettes. I testified that most people who smoke light cigarettes believe they are getting less tar and nicotine. I testified that, in the last 25 years, smokers relied on FTC ratings used in cigarette advertising to tell them what they will be consuming. I further testified that most people don't realize that low yield cigarettes determined by the FTC Method do not necessarily result in proportionally less nicotine being absorbed. It is a myth, I said, that people who smoke light cigarettes are necessarily going to get less nicotine.

I explained that the way in which a cigarette is smoked is probably the most important

http://legacy.library.ucsf.edu/tid/qzq07a00/pdf Document hosted at industrydocuments.ucsf.edu/docs/hqhl0001

determinant as to how much tar and nicotine is inhaled. Humans can compensate, I said, when smoking lighter cigarettes, by altering puff volume, puff duration, inhalation frequency, depth of inhalation and the number of cigarettes smoked. I stated that, as a result of these compensatory mechanisms, a low yield cigarette can actually result in a higher intake of nicotine. I discussed methods that were under the manufacturers' control that could contribute to the lowering of FTC machine ratings.

I presented the data that I mentioned earlier of three varieties of one brand family of cigarettes. I stated that what surprised us is that the variety advertised as having the lowest yield had the highest level of nicotine. I also showed the analysis of nicotine and tar data and stated that, while it has often been said that tar and nicotine travel together in cigarette smoke, the disparities in the trends of tar and nicotine raised the question of whether there was manipulation of nicotine. I concluded my testimony by stating that it was important for all of us to learn more about the way cigarettes are designed and what the tobacco industry's own research on nicotine demonstrated.

Q: I'd like you to turn your attention to informants. Did the investigation ever involve informants who were current or former employees of the cigarette manufacturers?

A: Yes.

Q: Did some of these informants ask that their identities be kept confidential?

A: Yes, they did.

Q: Why?

A: They were afraid. They were concerned about what actions the tobacco companies might take. Some of these informants were exceptionally nervous about talking to us. I saw that first hand. In fact, when I interviewed some of these informants, I knew them only by their code name. Some feared their lives could be made miserable if they talked to us.

Q: What role did informants play in the Food and Drug Administration investigation?

A: They focused us on where to look, on what questions to ask. They certainly helped

http://legacy.library.ucsf.edu/tid/qzq07a00/pdf Document hosted at industrydocuments.ucsf.edu/docs/hqhl0001

educate us. They put particular pieces of evidence in context. They led us to other individuals who might talk to us. In some cases, they provided documentary evidence.

Q: Did any of the confidential informants, after speaking to you on a confidential basis, ever subsequently reveal their identities publically?

A: Yes.

Q: Which informants?

A: I am not sure I can give you an exhaustive list. I do remember that Jeffrey Wigand, Victor DeNoble, Paul Mele, and Bill Farone did make their identities known subsequently. There may be others.

Q: Did an informant ever give the Food and Drug Administration suggestions relating to patents?

A: Yes.

Q: Did the informant who gave this information later make his identity known publicly?

A: Yes.

Q: What is this informant's name?

A: Dr. Jeffrey Wigand.

Q: What cigarette company had Dr. Wigand worked for?

A: Brown & Williamson.

Q: What did Dr. Wigand do when he worked at Brown & Williamson?

A: He was involved in research and development.

Q: Did you meet with Dr. Wigand during the FDA investigation of the cigarette industry?

A: Several times in my office.

Q: What was his demeanor?

A: As I alluded to before, he was exceptionally anxious.

http://legacy.library.ucsf.edu/tid/qzq07a00/pdf
Guttentag http://www.industrydocuments.ucsf.edu/docs/hqhl0001

Q: Did you consider him a reliable source of information?

A: My general attitude was that I did not consider any informant reliable unless I could corroborate what the informant told us. The information that Dr. Wigand gave us concerning our investigation was reliable.

Q: Why did you consider Dr. Wigand a reliable source?

A: He pointed us in certain directions–told us about certain activities of Brown & Williamson–that we were able to verify.

Q: What information were you able to corroborate?

A: He told us about certain practices–projects–at Brown & Williamson; Company Projects, for example, that included the use of both conventional breeding and genetic techniques to produce a high nicotine tobacco plant. We were able to substantiate that these projects had been undertaken.

Q: Did Dr. Wigand ever provide you with information concerning the FDA investigation that you later discovered was false?

A: I believe the answer to that question is no. Furthermore, the information that Dr. Wigand led us to has been on the public record now for a decade.

Q: What, if anything, did Dr. Wigand say to the FDA relating to patents?

A: My recollection is that he told us to look for patents for high-nicotine tobacco that was produced by a combination of conventional breeding and genetic engineering techniques.

Q: Did the Food and Drug Administration look for such patents?

A: Yes.

Q: What did the Food and Drug Administration find, if anything?

A: Our research librarian searched patent databases. We located a patent filed in Brazil written in Portuguese for a higher than normal nicotine tobacco plant.

Q: Dr. Kessler, please turn your attention to U.S. Exhibit 88,087. What is this exhibit?

A: This is a copy of the top of the Brazilian patent that we found.

http://legacy.library.ucsf.edu/tid/qzq07a00/pdf Document hosted at industrydocuments.ucsf.edu/docs/hqhl0001

Q: What is Y-1?

A: Y-1 is the name that was given to the high-nicotine tobacco plant that was produced by both conventional practices and genetic engineering techniques.

Q: What connection, if any, exists between this Brazilian patent that the Food and Drug Administration found and Y-1?

A: The Brazilian patent is for the Y-1 high-nicotine tobacco plant.

Q: You testified that this patent was written in Portuguese. How did you discern what statements were contained in the patent?

A: We had the document translated by two independent means: one, I believe, was an official translation done by the State Department, the second was done by an FDA employee who spoke and read fluent Portuguese.

Q: What was the nicotine concentration of Y-1 relative to conventional tobaccos?

A: According to the patent, Y-1 had approximately six percent by weight nicotine content in the tobacco leaf, which was significantly higher than other varieties of tobacco.

Q: Who held this Brazilian patent for Y-1?

A: It was held by Brown & Williamson Tobacco Company. The inventors were employees of Brown & Williamson and one of Brown & Williamson's contractors, DNAP Plant Technology.

Q: What other patent documents, if any, did the FDA discover relating to Y-1?

A: We were able to find a patent application and related documents filed in the United States.

Q: What did this patent application and any related documents relate to?

A: It was for Y-1. The patent was not approved. Brown & Williamson filed an appeal, but then abandoned its application.

Q: Please direct your attention to U.S. Exhibit 88,089. What is this exhibit?

A: This is a patent application.

http://legacy.library.ucsf.edu/tid/qzq07a00/pdf
Digitized by the Internet Archive in 2014 http://www.industrydocuments.ucsf.edu/docs/hqhl0001

Q: What is stated, if anything, on the fourth page of U.S. Exhibit 88,089 regarding the name and characteristics of this tobacco?

A: It states that the present invention relates to a new and genetically-stable variety of tobacco plant–more specifically, a new variety of flue-cured tobacco–that combines both a high nicotine content and good growing characteristics. This variety was found to be pleasant and acceptable in taste and aroma, contrary to other high nicotine content tobaccos. It states that the nicotine content of the leaf of this new tobacco plant is generally greater than about 6% by weight, which is significantly higher than any standard commercially-grown tobacco variety. It states that the name that has been applied to this new variety of tobacco is Y-1.

Q: What discussions did the FDA have with Brown & Williamson representatives on the issue of whether Brown & Williamson had engaged in any endeavor to alter the nicotine content of the tobacco, including breeding?

A: We specifically asked whether the company had engaged in any breeding of tobacco to control nicotine levels. Brown & Williamson representatives told us the answer was no, they had not. In-house counsel, Kendrick Wells, qualified the statement to say that they might have provided some money for university studies. We also asked them whether it was feasible to do that, and they said that it wasn't feasible to increase nicotine levels in tobacco because of certain voluntary agreements the industry had entered into that would not allow them to grow or sell higher nicotine tobaccos in the United States.

Q: When did these discussions with Brown & Williamson representatives occur?

A: I believe in May 1994.

Q: Did Brown & Williamson later admit that what representatives of Brown & Williamson told the FDA during these discussions was not true?

A: When confronted with evidence that we knew that Y-1 high nicotine tobacco was grown in Brazil and shipped into the United States, company representatives admitted in a meeting at FDA headquarters in June 1994, that they had engaged in growing, breeding and genetic testing

http://legacy.library.ucsf.edu/tid/qzq07a00/pdf
Digitized by the Industry Documents Library
http://www.industrydocuments.ucsf.edu/docs/hqhl0001

of high nicotine tobacco plants. Furthermore, they told us that they were specifically interested in maintaining the nicotine levels in tobacco, while lowering tar levels. They admitted to manipulating nicotine levels in Y-1.

Q: What other evidence, if any, did the FDA discover relating to Y-1?

A: We learned that Brown & Williamson had an inventory of between 3.5 and 4 million pounds of Y-1 tobacco with more Y-1 tobacco in inventory in Brazil. We also learned that it was used in some five varieties of American cigarettes that were sold commercially. My understanding was that, with our investigation underway, the company was trying to use it up as quickly as possible. I later saw documentation written several days after the tobacco CEOs testified in April 1994, from some Brown & Williamson officials in the United States to colleagues in Brazil, saying that they no longer had a "requirement" for Y-1 tobacco. Another document I later saw described blending options to the deplete their Y-1 inventory.

We further learned that the appeal on the U.S. patent application was abandoned approximately one week before my first testimony on tobacco in front of the House Health and Environment Subcommittee.

We learned that seeds of Y-1 were shipped from the United States to Brazil at a time through which such shipments would have violated U.S. law.

Q: How many Brown & Williamson brands sold in the United States, if any, had contained Y-1 tobacco?

A: I believe I testified there were approximately five varieties of Brown & Williamson cigarettes that contained Y-1 tobacco. I believe they probably included varieties that were part of the Viceroy, Richland and Raleigh brand families.

Q: Please turn to U.S. Exhibit 21,027. What is this exhibit?

A: This is a facsimile transmission between two Brown & Williams employees, R.R. Black and E.E. Kohnhorst. The document being transmitted is a list of products with Y-1. The second page has two headings. One heading is "Products with Y1ET," which lists five brands of Brown

http://legacy.library.ucsf.edu/tid/qzq07a00/pdf
Created: http://www.industrydocuments.ucsf.edu/docs/hqhl0001

& Williamson cigarettes. A second heading is titled "Licensed Product (With Y-1 Strip)," and lists an international brand of Brown & Williamson cigarettes.

Q: Is U.S. Exhibit 21,027 consistent with what the FDA discovered regarding Brown & Williamson's use of Y-1 tobacco in the brands it manufactured and sold in the United States?

A: Yes.

Q: Please turn your attention to U.S. Exhibit 20,831. What is this exhibit?

A: U.S. Exhibit 20,831 is a Brown & Williamson internal memo dated July 16, 1985, with the subject "Status of High Nicotine Tobacco Evaluation/377." The document is from Dr. B.B. Chakraborty to Mr. M.L. Reynolds.

Q: Did Brown & Williamson provide this document to the FDA during the investigation of the cigarette industry that occurred while you were FDA Commissioner?

A: I am not aware of Brown & Williamson having provided this document to us during the course of the investigation.

Q: To what extent, if any, is U.S. Exhibit 20,831 consistent with the findings of the FDA relating to nicotine manipulation and, in particular, Y-1?

A: It is consistent. The document analyzes cigarettes designed with Y-1 tobaccos and states: "[T]he tar to nicotine ratios of these samples are 25 to 30% lower than those of the corresponding Merit styles." The document states "[t]his demonstrates that by using high-nicotine tobaccos, the tar to nicotine ratios in smoke can indeed be altered."

Q: Now I would like to discuss the topic of freebasing. What is freebasing?

A: I can give you a scientific definition of the term "free-base." Freebasing is a term, I believe, that has entered our vocabulary over the last several decades. My understanding of the term freebasing, from what I learned at the FDA during our investigation of tobacco, was that it entailed the use of a chemical to increase the amount of a drug in the "free-base" form.

Q: How do drugs in "free-base" form differ, if at all, from the same drugs in non-"free-

http://legacy.library.ucsf.edu/tid/qzq07a00/pdf Document hosted at industrydocuments.ucsf.edu/docs/hqhl0001

base" form?

A: Based on what I learned at the Agency, increasing the percentage of drugs in the "free-base" form may increase the rate of absorption of the drug–how fast a drug gets delivered to the body and organs such as the brain. My further understanding is that this increased rate of absorption may be responsible for an increased "kick" that is associated with the "free-base" form.

Q: What references, if any, did you see to nicotine in the "free-base" form– during the FDA investigation of the cigarette industry–in the documents of the cigarette manufacturers who are defendants in this case?

My recollection is that words like "free," "unbound," "unprotonated," or "extractable" sometimes were used in a similar manner. The bottom line is that it is possible to change the chemical form of a drug to provide increased "kick."

Q: Did the Food and Drug Administration–while you were FDA Commissioner–investigate the issue of freebasing during its investigation of the cigarette industry?

A: We did not set out to investigate the issue of freebasing. We did investigate the cigarette manufacturers' use of chemicals to increase the amount of "free-base" or "free-nicotine" in cigarette smoke. We sought to learn about this practice.

Q: How did you, as the Food and Drug Administration Commissioner, seek to educate yourself about freebasing during this investigation of the cigarette industry?

A: I spoke to Jack Henningfield, an expert in the field. I also remember speaking to Jeffery Wigand and Bill Farone who were former tobacco company scientists who were willing to talk to us.

Q: Why, if at all, was the issue of freebasing important to the FDA investigation?

A: It is important for the Court to understand that the issue of freebasing in and of itself was not the issue for the agency. It was not whether the companies were right or wrong to be doing

http://legacy.library.ucsf.edu/tid/qzq07a00/pdf Document hosted at industrydocuments.ucsf.edu/docs/hqhl0001

work on modifying the percentage of free nicotine. What was important to the agency was whether the companies understood that nicotine was a drug and were treating it as such. If they were doing work on altering the nicotine molecule, that went to the question of whether they knew that nicotine in cigarettes was a drug.

Q: What was your reaction when it was first suggested during the FDA investigation that the cigarette industry may be designing their products to freebase nicotine?

A: At first, we saw evidence of the use of chemicals to produce more "free nicotine." When I discussed this evidence with one of our experts, Jack Henningfield, he matter-of-factly used the term freebasing to characterize this practice. My first reaction was somewhat incredulous, because freebasing had negative connotations with regard to crack cocaine. However, through the course of the investigation, industry documents indicated to me that some in the industry believed that "free nicotine" was associated with increased "kick."

Q: How did the FDA obtain knowledge about the use of bases to increase "free nicotine"?

A: My recollection is that one of the first times I heard about the use of bases to increase "free nicotine" was from Jeffery Wigand, Brown & Williamson scientist, talking to us at the time confidentially. We subsequently received a Brown & Williamson company handbook that specifically discussed the use of bases to increase "free nicotine," and its role as an "impact booster" and to increase satisfaction. Later on we saw documents from other companies also talking about this practice.

Q: Now I would like to discuss one document relating to this issue. Turn your attention to U.S. Exhibit 86,908. What is this exhibit?

A: It is a Brown & Williamson tobacco corporation document titled "Root Technology: A Handbook for Leaf Blenders and Product Developers." It is dated February 1991.

Q: How do you know it is a Brown & Williamson document?

A: It says so on the cover page.

http://legacy.library.ucsf.edu/tid/qzq07a00/pdf
Digitized by http://www.industrydocuments.ucsf.edu/docs/hqhl0001

Q: Is this document discussed in the FDA Final Rule?

A: Yes; I believe it is.

Q: How, if at all, was the Handbook for Leaf Blenders significant to the FDA investigation?

A: The handbook was titled "Root Technology." My understanding, I think from Wigand, was that those were code words for ammonia technology. The purpose of the handbook was to describe the different ways ammonia technology was then being used by companies in cigarette design and how ammonia technology could be further incorporated in cigarette design.

The documents discussed the various uses for ammonia in cigarettes. One part of the document still remains in my head today. It talked about how ammonia can liberate free nicotine from the blend. It specifically used the term "free" nicotine and associated "free" nicotine with increases in impact and satisfaction.

We came to understand that the use of "free" nicotine was another potential approach for companies to be able to reduce tar, while maintaining adequate nicotine for the smoker. In this approach, rather than just increasing total nicotine concentration in the cigarette, alterations in the chemistry of nicotine would result in increases in "satisfaction" reported by the smoker.

The tobacco companies spent considerable time focusing on increasing the effectiveness of nicotine delivery in light cigarettes. By increasing the amount of nicotine in the "free" form, which, according to the Leaf Blenders' handbook, increased the impact and satisfaction reported by smokers, the companies could potentially satisfy customers' need for nicotine, even if the total amounts of nicotine delivered was reduced.

Q: For now, tell the Court generally what the FDA concluded based on industry documents as to whether defendants designed their cigarettes to "free-base" nicotine?

A: The FDA concluded that cigarette manufactures conducted product research and development on chemical manipulation of nicotine. The evidence in the record also supported

http://legacy.library.ucsf.edu/tid/qzq07a00/pdf
Document hosted at industrydocuments.ucsf.edu/docs/hqhl0001

the finding that the manufactures knew that their competitors used chemicals to increase the delivery of "free" nicotine.

Q: Dr. Kessler, I would like you review two additional exhibits that may relate to free nicotine – U.S. Exhibits 55,968 and 88,091. Did you review these documents in your official capacity as FDA Commissioner?

A: Yes, I believe I did.

Q: Are these the same documents that are cited in the FDA Final Rule?

A: Yes.

Q: How, if at all, did the Food and Drug Administration consider the information in these documents concerning the role of "free," or "extractable," nicotine with respect to cigarette impact to be significant to the FDA investigation of the cigarette industry?

A: These documents demonstrate that British American Tobacco Company did considerable research to enhance nicotine deliveries, including the use of chemical manipulation of tobacco. U.S. Exhibit 55,968, which is titled "Further Work on Extractable Nicotine," demonstrates that the cigarette company understood that the amount of "extractable" nicotine–a term that is similar to the term "free nicotine"–in the smoke correlates better with the "reaction of a smoker to strength of the smoke than to the total nicotine content." Thus, it is this chemically altered type of nicotine which, according to this document, is more closely tied with the effect on the smoker. Furthermore, the document states "that the increased smoker response is associated with nicotine reaching the brain more quickly." U.S. Exhibit 88,091 demonstrates that the addition of a specific chemical which is a base to filters results in an increased delivery of "extractable nicotine."

Q: Dr. Kessler, I would now like you to turn to U.S. Exhibits 20,820 and 20,840. What are these documents?

A: U.S. Exhibit 20,820 is a document entitled "Technology: Ammoniation," which chronicles the use of ammonia in tobacco over several decades, focusing primarily on its use in

http://legacy.library.ucsf.edu/tid/qzq07a00/pdf Document hosted at industrydocuments.ucsf.edu/docs/hqhl0001

R.J. Reynolds cigarette products. U.S. Exhibit 20,840 is an R.J. Reynolds document stamped "Secret" and titled "Implications and Activities Arising from Correlation of pH With Nicotine Impact, Other smoke Qualities and Cigarette Sales."

Q: Did you see either of these documents in your official capacity as Commissioner of the FDA?

A: I believe I saw U.S. Exhibit 20,840 during my work at the FDA.

Q: How, if at all is the information in U.S. Exhibits 20,820 and 20,840 significant to the FDA investigation?

A: The significance of U.S. Exhibit 20,820 is several-fold. First, it documents that ammonia has been used intentionally in tobacco products for at least four decades. Second, it states that the product characteristics of ammoniation include, among other attributes, "stronger physiological impact with less harshness." Third, it states that ammoniation product characteristics include "cleaner taste with more free nicotine." Fourth, it documents that at least some in the industry understood that ammoniation resulted in more free nicotine, and also had physiological consequences. Fifth, it states that Philip Morris used ammoniation beginning in 1965, and increased the its use until 1974. This document states that "this time period corresponds to the dramatic sales increase Philip Morris made from 1965 to 1974." U.S. Exhibit 20,840 provides further support that R.J. Reynolds believed that there was a "strongly positive correlation between 'free' nicotine in smoke . . . and market share performance" of Philip Morris's Marlboro cigarette. It also equates increasing the pH with enhancing nicotine "kick." Furthermore, this document states that the then-current Marlboro "despite a two-thirds reduction in smoke 'tar' and nicotine over the years, calculates to have essentially the same amount of 'free' nicotine in its smoke as did the early Winston." According to R.J. Reynolds in this document, Marlboro had almost three-times the amount of free nicotine in the smoke that R.J. Reynolds's brand Winston had in the smoke, despite the fact that the tar and nicotine numbers for Marlboro were less than Winston. I believe a fair interpretation of this document is that R.J.

http://legacy.library.ucsf.edu/tid/qzq07a00/pdf Document hosted at industrydocuments.ucsf.edu/docs/hqhl0001

Reynolds believed that Marlboro, a cigarette of its competitor, Philip Morris, had higher smoke pH, which was associated with increased "free" nicotine, that Marlboro had more "free" nicotine in the smoke, that free nicotine equated with "more instantaneous nicotine kick than our brands," and that a higher smoke pH cigarette with more free nicotine in the smoke correlated with increased sales.

Q: To what extent, if at all, is the information in U.S. Exhibits 20,820 and 20,840 consistent with the conclusions of the FDA relating to the use of "free nicotine" by the members of the cigarette industry who are defendants in this case?

A: I believe these documents support FDA's findings regarding the use of ammonia in cigarettes.

Q: Dr. Kessler, please turn your attention to Demonstrative Exhibit DK003. What is this exhibit?

A: This is a replication of a page from U.S. Exhibit 20,840 with the Bates number 511223482. The quote on the bottom is at Bates number 509018864 of U.S. Exhibit 20,820.

Q: What is the source of the information in DK003?

A: There are two sources for the information in DK003. The first is a replication of an R.J. Reynolds chart contained in the "Secret" R.J. Reynolds report entitled "Implications and Activities Arising from Correlations of Smoke pH With Impact, Other Smoke Qualities, and Cigarette Sales." The quote on the bottom is from U.S. Exhibit 20,820, at Bates number 509018864.

Q: Please explain to the Court the significance, if any, of the data in DK003 relative to the "free nicotine" issues investigated by the FDA during the investigation of the cigarette industry that occurred while you were FDA Commissioner.

A: The significance of the data in DK003 is that it demonstrates that R.J. Reynolds believed that Philip Morris's Marlboro utilized more ammonia, had higher smoke pH levels, and thus had more free nicotine in the smoke. R.J. Reynolds believed that a significant increase in sales

http://legacy.library.ucsf.edu/tid/qzq07a00/pdf
Document hosted at industrydocuments.ucsf.edu/docs/hqhl0001

corresponded to the increase in free nicotine in the smoke. It supports FDA's finding that R.J. Reynolds believed that ammonia and free nicotine were related, and they result in increased sales.

Q: Dr. Kessler, please review U.S. Exhibits 20,496, 37,310 and 37,312. What are these exhibits?

A: U.S. Exhibit 37,310 includes a fax cover page and a handwritten document from F. Gullotta at INBIFO Contract Research to C. Hayes at Philip Morris, dated June 23, 1994. The title on the next page is stamped "DRAFT" and reads "The Effects of Cigarette Smoke 'pH' on Nicotine Delivery and Subjective Evaluations." U.S. Exhibit 37,312 appears similar to U.S. Exhibit 37,310, except it does not have the fax cover page. U.S. Exhibit 20,496 is also similar to U.S. Exhibits 37,310 and 37,312, and is a typed version typed and sent one day later. The recipient of U.S. Exhibit 20,496 was Dr. Cathy Ellis, Director, Research at Philip Morris.

Q: What relationship, if any, do U.S. Exhibits 20,496, 37,310 and 37,312 have to the testimony that you gave before the United States Congress as FDA Commissioner on the issue of cigarettes?

A: We testified, according to an industry handbook, that ammonia "liberates free nicotine," which is "associated with increases in impact and satisfaction by the smoker," when added to a tobacco blend. U.S. Exhibit 37,310 and 37,312 state that the "form"–and that word is underlined–not the amount of nicotine, is changed at higher pH's; similar statements are reflected in U.S. Exhibit 20,496.

Q: What significance, if any, do U.S. Exhibits 20,496, 37,310 and 37,312 have to the FDA investigation of the cigarette industry that occurred while you were FDA Commissioner?

A: These documents from Frank Gullotta and transmitted to Director of Research at Philip Morris after my testimony in 1994 show that Philip Morris knew that "the form, not the amount

http://legacy.library.ucsf.edu/tid/qzq07a00/pdf
Digitized by http://www.industrydocuments.ucsf.edu/docs/hqhl0001

of the nicotine is changed" when bases are added to tobacco filler. Gullotta reported that "[w]e found that increased filler pH" (more base) "resulted in enhanced electrophysiological" (more brain wave activity) "and subjective effects." Mr. Gullotta of Philip Morris "interpreted these data to mean that higher pHs resulted in more unprotonated nicotine" (free nicotine)–"a more physiologically effective form."

Q: Dr. Kessler, please turn your attention to U.S. Exhibits 51,496 and 85,446. Please describe these exhibits.

A: U.S. Exhibit 51,496 is a January 4, 1980 Brown & Williamson document titled "File Note"-- "Observation Of Free Nicotine Changes In Tobacco Smoke/#528" initialed by C.F. Gregory. U.S. Exhibit 85,446 is a document which is similar to U.S. Exhibit 51,496; it does not include the fax page.

Q: Please explain the relevance of these documents, if any, to the issues examined by the FDA during its investigation of the cigarette industry?

A: U.S. Exhibit 51,496 shows that Brown & Williamson "[f]or some time" had "been aware of the relationship between smoke pH (TPM) and free nicotine delivered in tobacco smoke." The company also understood that this was important "as the industry moves toward lower nicotine products." The document then considers the following example from a relative standpoint: it compares Marlboro 85 against Merit. Marlboro 85, according to this document, has 1.15 mg. total nicotine delivered, 0.33 mg. free nicotine, 28.7% free nicotine and a smoke pH of 5.9. Merit has 0.64 mg. total nicotine, 0.32 mg. free nicotine, 50.0% free nicotine, and a smoke pH of 6.4. This example demonstrates that Merit, which has a higher smoke pH, has a higher percent free nicotine than Marlboro. From a smoking machine analysis, Merit has a little more than half the amount of total nicotine delivered as Marlboro, but, according to the document, has a nearly identical amount of free nicotine in the smoke. The document states: "In theory, a person smoking these cigarettes would not find an appreciable difference in the physiological satisfaction from either, based on the amount of free nicotine delivered." The

http://legacy.library.ucsf.edu/tid/qzq07a00/pdf Generated by http://www.industrydocuments.ucsf.edu/docs/hqhl0001

words "sensory impact?" versus "pharmacological" are written in next to the word "physiological." The document goes on to state: "It appears that we have sufficient expertise available to 'build' a lowered mg tar cigarette which will deliver as much 'free nicotine' as a Marlboro, Winston or Kent, without increasing the total nicotine delivery above that of a 'Light' product." The document also states "there are products already being marketed that deliver high percentage 'free nicotine' levels in smoke, i.e., Merit, Now."

Q: What did the FDA conclude, if anything, based on industry documents, as to whether there is a correlation between free nicotine in commercially-marketed cigarette brands and the cigarette sales of those brands?

A: Based on our review of documents, certain of the tobacco companies believed, demonstrated, and reported that there was a correlation between "free" nicotine in commercially-marketed cigarette brands and the sale of those brands. The FDA did not itself do those studies, nor was that the issue for the agency. If the tobacco companies chemically altered nicotine with the intent of increasing its effectiveness, that was important with regard to the FDA's determination of whether nicotine was a drug.

Q: To your knowledge, what have the defendants in this case done, if anything, to tell the public that defendants sell cigarettes designed to freebase nicotine?

A: My recollection is that the defendants have steadfastly denied that tobacco processing practices have any effect on the amount of "free" nicotine in the smoke.

Q: Now I would like to talk to you about Drs. Victor DeNoble and Paul Mele. Who is Dr. Victor DeNoble?

A: Victor DeNoble is a behavioral psychologist who was employed by Philip Morris in the early 1980s. DeNoble served as a confidential informant early on in our investigation, he then went public testifying before a congressional hearing.

Q: Who is Dr. Paul Mele?

A: Paul Mele was also a scientist employed by Philip Morris, who worked with Victor

http://legacy.library.ucsf.edu/tid/qzq07a00/pdf
Additional digitized by www.industrydocuments.ucsf.edu/docs/hqhl0001

DeNoble also in the early 1980s. He too served as a confidential informant early on in our investigation and then testified before a congressional hearing.

Q: Describe generally the context of the communications, if any, you personally had with Drs. DeNoble and Mele during the Food and Drug Administration investigation.

A: I met with Dr. DeNoble personally several times. My first communication with Dr. Mele was a speaker phone conversation between Dr. Mele, myself, and members of the tobacco team. Subsequently, I talked with Dr. Mele in person.

Q: Describe how, if at all, your conversations with Drs. DeNoble and Mele during the FDA investigation related to scientific research Drs. DeNoble and Mele had done for Philip Morris USA.

A: Drs. DeNoble and Mele's work at Philip Morris in the early 1980s focused on whether laboratory animals, rats, would "self-administer" nicotine. Self-administration is a term that describes whether a subject or an animal would "work" to receive intravenous injections of a drug–whether they would press a lever to receive a dose of the drug. Substances that are self-administered are said to be "reinforcing," which means that the use of the substance will likely result in further use. Laboratory animals reliably self-administer addictive drugs. Tests for self-administration are used by the Food and Drug Administration, the Drug Enforcement Administration and the National Institute on Drug Abuse to determine whether a substance has addictive properties and should be listed as a controlled substance. Demonstration of self-administration is one of the hallmark properties of addictive substances.

Drs. DeNoble and Mele were among the first scientists to demonstrate that rats will self-administer nicotine. We further learned that, on repeat occasions, Philip Morris company officials prevented Drs. DeNoble and Mele from publishing their work.

Drs. DeNoble and Mele also worked on finding alternative substances that could be used in cigarettes that were equally as "reinforcing" as nicotine. Earlier on in our investigation we saw patents owned by Philip Morris for chemically synthesized nicotine analogs–nicotine like

http://legacy.library.ucsf.edu/tid/qzq07a00/pdf
Digitized by the Internet Archive in 2014 http://www.industrydocuments.ucsf.edu/docs/hqhl0001

molecules. When I first saw that Philip Morris was involved in synthesizing nicotine like molecules, I did not understand why. In discussion with Drs. DeNoble and Mele, it became clear that Philip Morris was interested in finding nicotine like molecules that could be substituted for nicotine that did not possess the adverse effects on the heart that were associated with nicotine.

Drs. DeNoble and Mele also told me about certain compounds that had synergistic (where the sum of two things working together may be greater than the sum of the individual parts) properties. They stated they had data that a compound called acetaldehyde may enhance the reenforcing effect of nicotine.

Q: What evidence, if any, was the FDA able to identify to corroborate the information Drs. DeNoble and Mele provided regarding their self-administration research and their interactions with Philip Morris during and after their employment?

A: We were able to obtain information about the manuscripts that Drs. DeNoble and Mele submitted to the Journal of Psychopharmacology, from the Journal's editor, Dr. Herbert Barry. That information documented that it was Philip Morris that was having them withdraw the manuscripts before they were published. We subsequently obtained the manuscripts themselves.

Q: Did Drs. DeNoble or Mele provide you any information during the Food and Drug Administration investigation that you determined was not correct?

A: Not that I am aware of.

Q: Earlier you indicated that the FDA filed several documents relating to FDA's assertion of jurisdiction over tobacco products. Please turn to U.S. Exhibit 33,034. What is this Exhibit?

A: This document is FDA's Proposed Rule, Jurisdictional Analysis, Appendices and Related Federal Register Notices. The Proposed Rule is dated August 1995; the full document is dated August 1996. The Proposed Rule was published in the Federal Register on August 11, 1995.

Q: Turn to page 96 of this document. What, if any, conclusions does the FDA Proposed Rule reach here about self-administration?

http://legacy.library.ucsf.edu/tid/qzq07a00/pdf Document hosted at industrydocuments.ucsf.edu/docs/hqhl0001

A: First, that the "self-administration model is widely used to assess a drug's ability to induce and maintain drug seeking behavior in animals."

Second, "self-administration studies determine whether animals will press a lever to give themselves repeated doses of a test substance."

Third, "the ability of a substance to cause self-administration in animals demonstrates that the substance is a positive reinforcer, i.e. that it induces continued, compulsive use."

Fourth, "having a positive reinforcing effect in animals is one of the key pieces of predictive evidence that a substance will produce addiction."

Fifth, nicotine, "like many addictive drugs, such as cocaine, opiates, and hypnotics, has now been demonstrated through self-administration studies to be an effective positive reinforcer in animals."

Sixth, "this property of nicotine was not consistently demonstrated until the 1980s."

Seventh, "intermittent availability of nicotine, which parallels the pattern of cigarette smoking, will induce self-administration in animals, while continuous administration . . . is far less likely to do so." **Q: Are you aware of any of the cigarette manufacturers indicating that this research conducted by Drs. DeNoble and Mele was not valid scientifically?**

A: No.

Q: Are you aware of anyone else in the scientific community finding fault with this research by Drs. DeNoble and Mele?

A: No.

Q: Are you aware of *anyone* indicating that this research by Drs. DeNoble and Mele was not valid scientifically?

A: No.

Q: Dr. Kessler, before we move from our discussion of the information that Drs. DeNoble and Mele provided the FDA, I would like to show you a few documents that may bear on this topic. Please briefly review U.S. Exhibits 20,100; 20,199; 20,380; 20,398;

http://legacy.library.ucsf.edu/tid/qzq07a00/pdf
Digitized by the Internet Archive in 2014 http://www.industrydocuments.ucsf.edu/docs/hqhl0001

20,476; 22,708; 22,847; 35,826 and 36,743. What relationship, if any, do these documents have to the information that Drs. DeNoble and Mele provided the FDA?

A: They corroborate what Drs. Mele and DeNoble told the FDA.

Q: How?

A: First, they confirm that nicotine and acetaldehyde were both shown to be positive reinforcers and the reinforcing effects of nicotine under the experimental conditions were relatively weak compared to other reinforcers. Second, Philip Morris understood that tolerance to nicotine is a well-established fact. Third, self-administration is a primary criterion used by many people for assessing the "abuse liability" of a drug. Fourth, Philip Morris knew that DeNoble's research "strengthens the adverse case against nicotine as an addictive drug." Fifth, DeNoble did not visually observe a physical dependence to nicotine, but that their "gross observational procedure, which provided the basis for their opinions of physiological dependence, is subject to strong criticism." Sixth, DeNoble's work on "central nervous system pharmacological actions is clearly at variance with positions which the industry takes with regard to nicotine and smoking." Seventh, that the data generated by DeNoble was "a believable claim based on their data." Eighth, "research done by Frank Ryan indicated that acetaldehyde and nicotine data could be used to predict cigarette sales at a 96% accuracy." Ninth, that in 1994, DeNoble thought there was "an overwhelming body of evidence that nicotine does produce an addiction in humans." In the early 1980s, "there were some doubts" in DeNoble's mind "because the data wasn't there." These statements are consistent with what Drs. DeNoble and Mele told us during the FDA investigation. The above is not an exhaustive list of all statements in the documents you listed.

Q: Who is Dr. William A. Farone?

A: Dr. Farone is a scientist. He was director of applied research at Philip Morris in the late seventies and early eighties. He was responsible for understanding and developing cigarette technology at the company. Early on in our investigation he talked to the FDA confidentially.

http://legacy.library.ucsf.edu/tid/qzq07a00/pdf Document hosted at industrydocuments.ucsf.edu/docs/hqhl0001

Subsequently, he made his identity public.

Q: Describe the communications between Dr. Farone and the FDA during the FDA investigation of the cigarette industry.

A: I had multiple conversations with Dr. Farone, along with the tobacco team, by either conference call or speaker phone. Dr. Farone provided us with a detailed understanding of how cigarettes are made. He helped me understand how sophisticated the companies had become in designing cigarettes to assure adequate nicotine delivery. Dr. Farone made it clear that the cigarette industry understood that people smoked for the effect of nicotine. He also stated that nicotine was a pharmacologically (drug like) active component of cigarettes. He told me that in the late 1970s and early 1980s, the companies understood and had established that smokers required a minimal level of nicotine in a cigarette. Further, he stated that the tobacco industry studied and researched how to design and construct cigarettes to ensure acceptable nicotine levels. Dr. Farone told us that a major objective of the industry of the last several decades was to decrease the tar in the cigarette, while maintaining delivery of nicotine. The need of the industry to achieve pharmacologically active levels of nicotine in lighter cigarettes required the manufacturers to deliberately control the levels of nicotine in their product. Dr. Farone emphasized to us that industry controls nicotine levels by either modification or control of the tobacco blend or modification of the construction of the cigarette.

Q: Please explain how, if at all, the information Dr. Farone provided was useful to the FDA investigation of the cigarette industry.

A: I was struck by how sophisticated Dr. Farone said Philip Morris had become in delivering adequate levels of nicotine to consumers. Dr. Farone would talk about the chemical intricacies of tobacco smoke. He described in detail physical attributes of the particles that contain nicotine. He documented for the agency that the tobacco companies devoted enormous resources to delivering nicotine in their products. He confirmed for us that Philip Morris knew that, by using a higher nicotine tobacco in their lower tar cigarettes, they could achieve higher levels of nicotine

http://legacy.library.ucsf.edu/tid/qzq07a00/pdf
Digitized by the Internet Archive in 2014 http://www.industrydocuments.ucsf.edu/docs/hqhl0001

in their cigarettes. He described the intricacies of filter design that were aimed at predetermined nicotine/tar ratios. He also confirmed for us that Philip Morris conducted research into nicotine's effect on brain waves and brain receptors.

Dr. Farone made clear that the industry knew that cigarettes were a drug delivery device.

Q: Did you consider Dr. Farone a reliable source of information?

A: Yes.

Q: Why?

A: As a scientist, he was particularly precise in the information he gave us.

Q: How, if at all, were you able to corroborate information Dr. Farone provided to you during the FDA investigation of the cigarette industry?

A: The information that we received from Dr. Farone was corroborated from tobacco company documents that we reviewed.

Q: Did Dr. Farone ever provide you with any information that you discovered was false?

A: No. Furthermore, let me point out that Dr. Farone provided the Agency with a signed statement on the manipulation and control of nicotine and tar in the design and manufacture of cigarettes. That statement has been on the public record for nearly a decade. I am not aware of any inaccuracies in the information he provided.

Q: Who is Ian Uydess?

A: Ian Uydess worked as a research scientist at Philip Morris, and agreed to talk to us confidentially. He then made his identity public.

Q: Describe the communications between Dr. Uydess and the FDA during the FDA investigation of the cigarette industry.

A: I remember a long conversation between Dr. Uydess, myself, and the tobacco team. I have a recollection that I met Dr. Uydess in person in Rockville, Maryland, although I cannot be sure. He had a number of conversations and contacts with members of the tobacco team.

http://legacy.library.ucsf.edu/tid/qzq07a00/pdf
Guttids http://www.industrydocuments.ucsf.edu/docs/hqhl0001

Q: Please explain how, if at all, the information Dr. Uydess provided was useful to the FDA investigation of the cigarette industry.

A: Dr. Uydess told us about Philip Morris research that was taking place in Cologne, Germany. The research included human research involving brainwave testing (electroencephalograms) and smoking. I believe Dr. Uydess told us that this work by Frank Gullotta involved studying different levels of nicotine. Dr. Uydess also told us about how nicotine was an important consideration in the design, development and manufacturing of cigarettes, and how, when the companies designed a new or modified blend, they used their tobacco inventories much like a scientist would use a chemical stockroom. Dr. Uydess provided us with information about what Philip Morris knew about nicotine and how they designed their cigarettes.

Q: Did you consider Dr. Uydess a reliable source of information?

A: Yes.

Q: Why?

A: My impression in talking to Dr. Uydess was that he was a scientist who told us what he knew, and that he was careful to discuss only what he knew. Furthermore, Dr. Uydess provided us with a Declaration that was signed under penalty of perjury in 1996. That document has been on the public record now for more than eight years.

Q: To what extent, if any, were you able to corroborate information Dr. Uydess provided to you during the FDA investigation of the cigarette industry?

A: Dr. Uydess's statements to us were consistent with what we learned from other sources.

Q: Did Dr. Uydess ever provide you with any information that you discovered was false?

A: Not that I am aware of.

Q: During your communications with Drs. DeNoble, Mele, Farone, Uydess and Wigand, what understanding, if any, did they communicate to you that, by talking to the

http://legacy.library.ucsf.edu/tid/qzq07a00/pdf
Created: http://www.industrydocuments.ucsf.edu/docs/hqhl0001

FDA, they were risking being sued by their former employers in the cigarette industry?

A: I believe I had that sense. They were all fearful of the industry.

Q: At what point in time did the FDA begin to see more cigarette industry documents?

A: We began our investigation in February 1994. We did see a handful of industry documents early on, primarily from tobacco product liability cases that went to trial in the 1980s, especially the Cipollone case. In early May 1994, however, what I would consider the first large collection of tobacco industry documents in many years surfaced.

Q: Please provide an example of the types of documents you began to see in May 1994.

A: The first large set of documents that emerged in May 1994 were known as "the Brown & Williamson documents," and also known as "the Merrill Williams documents." These documents, that spanned decades, were primarily letters, internal company memoranda and research reports of Brown & Williamson and British American Tobacco. Many of the documents were written by cigarette company lawyers who focused, not only on activities at Brown & Williamson and British American Tobacco, but also on industry-wide activities, including the Tobacco Industry Research Committee, the Council for Tobacco Research, the Tobacco Institute, and the Committee of Counsel, which was comprised, I believe, of the general counsel from companies who are defendants in this case and outside counsel.

Another example included a large collection of Philip Morris behavioral and pharmacological research documents from a document archive in Houston, maintained by the non-profit group called "D.O.C.," which stood for "Doctors Ought to Care."

Q: Earlier we discussed your first testimony before the U.S. Congress as FDA Commissioner on the issue of cigarettes. Did you testify a second time before Congress on issues relating to the nicotine in cigarettes?

A: Yes.

Q: When?

A: On June 21, 1994.

http://legacy.library.ucsf.edu/tid/qzq07a00/pdf Document hosted at industrydocuments.ucsf.edu/docs/hqhl0001

Q: When did you, as Commissioner of the FDA, become convinced that the cigarette industry intended the nicotine in its cigarettes to function as a drug?

A: During the first several months of our investigation, I would say that I did not know where the evidence would lead. When I read tobacco industry documents in May of 1994 that were written in the 1960s where senior tobacco industry officials were writing statements such as "we are, then, in the business of selling nicotine, an addictive drug . . .," I knew that the level of evidence increased substantially. The full picture–that key tobacco industry officials knew that nicotine was a drug and said it privately–emerged over the course of our investigation and rulemaking.

Q: After the second time you testified, as FDA Commissioner, before Congress on the issue of cigarettes, what did the FDA examine next?

A: FDA began to investigate the marketing practices of the tobacco industry–this was a second phase of our investigation.

Q: Describe why you began the second phase of the investigation.

A: First, if FDA were to assert jurisdiction that nicotine was a drug, we would have to decide what type of regulations to put into effect. It made no practical sense to ban the product. So we had to determine what was an appropriate regulatory framework. The specific provisions of the FDA statute that we were dealing with gave the FDA authority to regulate the sale, use and distribution of the product. That meant understanding the marketing practices of the industry. Second, during the summer of 1994, I read certain tobacco industry documents that described how children and adolescents become addicted through their child and adolescent years. Since we were focused, in part, on the addictive properties of nicotine, it was important to understand the consequences of the industry's marketing practices.

Q: To what extent, if any, did you rely on your background as a pediatrician when examining, as FDA Commissioner, the issue of youth smoking?

A: I think my background as a pediatrician was important.

http://legacy.library.ucsf.edu/tid/qzq07a00/pdf Document hosted at industrydocuments.ucsf.edu/docs/hqhl0001

Q: Please explain.

A: As I read industry documents, what was useful to me was my understanding about the development of children and adolescents. It became clear to me from reading the industry documents that these documents indicated that addiction to nicotine set in over a period of years–that that child who begins to experiment at 12 or 13 could become addicted within the next several years. I may not have come to understand that nicotine addiction begins as a pediatric disease if I had not been trained in pediatrics.

Q: What did you, as FDA Commissioner, conclude, if anything, with regard to cigarette smoking and young people?

A: There is a window period when children and adolescents begin to smoke. While that window is open, nearly 90% of people who will become addicted begin to use tobacco. When that window closes, far fewer people begin to smoke. Furthermore, from reading industry documents, I became convinced that some in the industry understood that youth smokers were one of the major critical determinants of success for the cigarette industry.

Q: Please examine Demonstrative Exhibit DK004. Please describe DK004 and the information on which it is based.

A: It is a pie-chart and a quote from the 1994 Surgeon General's Report, titled "Preventing Tobacco Use Among Young People." The pie-chart is based on data in Table 7 on page 65, and reflects at what ages young people try their first cigarette. More specifically, the pie-chart reflects the percentages of recalled age at which a respondent first tried a cigarette–of total subjects who had ever smoked daily. The quote is a conclusion of the 1994 Report of the Surgeon General.

Q: Please explain to the Court how this information related to the FDA investigation of the cigarette industry that you led as FDA Commissioner.

A: The fact that most smokers begin as children and adolescents led the Agency to propose and adopt regulations that were aimed at reducing the number of young people who smoke.

http://legacy.library.ucsf.edu/tid/qzq07a00/pdf
Document hosted at industrydocuments.ucsf.edu/docs/hqhl0001

Q: Please turn your attention to U.S. Exhibits 20,659 and 20,708. What are these exhibits?

A: They are documents written by Claude E. Teague, Jr. in 1972 and 1973. One is titled "Research Planning Memorandum on the Nature of the Tobacco Business and the Crucial Role of Nicotine Therein." The other is a document titled "Research Planning Memorandum on Some Thoughts About New Brands of Cigarettes for the Youth Market."

Q: Directing you to U.S. Exhibit 21,605. What is this exhibit?

A: It is an R.J. Reynolds research department report dated March 15, 1976, called "Planning Assumptions and Forecast for the Period 1977-1986 for R.J. Reynolds Tobacco Company."

Q: Did you, as FDA Commissioner, review these documents during the FDA investigation of the cigarette industry?

A: I believe I did.

Q: Please describe for the Court the impact, if any, these three documents had on the FDA investigation of the cigarette industry while you were FDA Commissioner.

A: U.S. Exhibit 21,605 stated that "evidence is now available to indicate that the 14 to 18 year old group is an increasing segment of the smoking population." The document went on to state that "RJR-T must soon establish a successful new brand in this market if our position in the industry is to be maintained over the long term."

In U.S. Exhibit 20,708, Dr. Teague, who worked at R.J. Reynolds, wrote "Realistically, if our Company is to survive and prosper over the long term, we must get our share of the youth market." Dr. Teague discussed what goes into making "youth brands": "For the pre-smoker and 'learner' the physical effects of smoking are largely unknown, unneeded, and actually quite unpleasant or awkward." Once that "learning is over," Dr. Teague wrote, "the physical effects become of overriding importance in the desirability to the confirmed smoker."

U.S. Exhibit 20,659 contains a statement of Dr. Teague that I remember to this day: "[I]f we are to attract the non-smoker or pre-smoker, there is nothing in this type of product that he

http://legacy.library.ucsf.edu/tid/qzq07a00/pdf
Digitized by the Internet Archive in 2014 http://www.industrydocuments.ucsf.edu/docs/hqhl0001

would currently understand or desire. . . . Instead, we somehow must convince him with wholly irrational reasons that he should try smoking . . . ."

Q: After examining issues of addiction, nicotine pharmacology, nicotine manipulation and youth smoking, did the FDA–and you as FDA Commissioner–look into any other aspects of the cigarette industry before promulgating the Rule asserting jurisdiction over cigarettes?

A: Yes.

Q: Why?

A: We wanted to understand the industry's statements that nicotine was not addictive and that they did not manipulate nicotine levels in the context of the historical record. We sought to understand these issues in the context of the industry's statements and strategies involving smoking and health more broadly, so we examined documents that related to how the industry dealt with smoking and health issues over four decades.

Q: Which aspects did the Food and Drug Administration examine?

A: We looked at documents written in the 1950s, 1960s, 1970s and 1980s dealing with such issues as the Tobacco Industry Research Council, Hill & Knowlton, the Committee of Counsel, and the Council for Tobacco Research.

Q: Dr. Kessler, earlier you testified that Hill & Knowlton was a public relations organization that worked with the cigarette industry. To what extent, if any, did the FDA examine documents relating to Hill & Knowlton to gain information relating to the activities of the Tobacco Industry Research Council and the Council for Tobacco Research?

A: We did seek and were able to obtain documents relating to Hill & Knowlton's relationship to the tobacco industry and, more specifically, to both the Tobacco Industry Research Council and the Council for Tobacco Research.

Q: Where did the FDA get the Hill & Knowlton documents that it reviewed?

http://legacy.library.ucsf.edu/tid/qzq07a00/pdf
Document hosted at industrydocuments.ucsf.edu/docs/hqhl0001

A: I asked FDA's historian to contact the Wisconsin Historical Society to obtain John Hill's papers. Additional sources of documents relating to Hill & Knowlton were obtained as part of the Brown & Williamson documents. To my knowledge, those were the major sources; there may have been other Hill & Knowlton documents secured as part of other document sets.

Q: What Hill & Knowlton documents from the Wisconsin Historical Society, if any, did you personally review during the FDA investigation of the cigarette industry?

A: My recollection is that I either read or scanned the Hill & Knowlton documents that I was given by the FDA historian.

Q: Please review U.S. Exhibits 87,224; 87,225; 88,043; 88,171; 88,178; 88,179; 88,191; 88,194; 88,196; 88,209; 88,360; 88,386; 88,388; 88,394; 88,402; and 88,410. What are these exhibits?

A: I believe these are documents from the John Hill archives dating back to the 1950s, and reflect the work that Hill & Knowlton did for the cigarette industry in developing the industry's strategy on smoking and cancer.

Q: Did you also, as FDA Commissioner, personally review other documents relating to the Tobacco Industry Research Council and the Council for Tobacco Research during the FDA investigation of the cigarette industry?

A: Yes. They were part of the Brown & Williamson documents. There may have also been documents from other tobacco product liability cases that discussed the Tobacco Industry Research Council and the Council for Tobacco Research.

Q: Please review U.S. Exhibits 20,049; 20,144; 20,467; 20,995; 21,211; and 21,395. What are these exhibits?

A: These are cigarette industry documents dating from the 1960s to the 1970s that relate to either Hill & Knowlton or the Council for Tobacco Research.

Q: Dr. Kessler, please turn your attention to U.S. Exhibit 20,467. What is this exhibit?

A: This is a meeting of cigarette industry lawyers and company officials that took place in

http://legacy.library.ucsf.edu/tid/qzq07a00/pdf http://www.industrydocuments.ucsf.edu/docs/hqhl0001

New York on November 17, 1978.

Q: Directing your attention to page two of U.S. Exhibit 20,467, which bears Bates number 2045752107, what does this document state with regard to the reason CTR was set up?

A: The second page of the document states that CTR "was set up as an industry 'shield' in 1954," which helped "legal counsel by giving advice and technical information," "supplied spokesmen for the industry at Congressional hearings," and provided "a base for introduction of witnesses."

Q: And what does U.S. Exhibit 20,467 state on the same page, if anything, relating to the role of CTR with respect to "special projects"?

A: The document states "on these projects, CTR has acted as a 'front.'"

Q: What are "special projects"?

A: My understanding is that these were research grants funded by CTR, selected by the lawyers, but not reviewed by CTR's Scientific Advisory Board.

Q: Who is Merrill Williams?

A: Merrill Williams was a paralegal at a law firm in Louisville, Kentucky. The law firm was hired to categorize and review internal cigarette company documents. Williams was assigned to work on that project. He took internal cigarette company documents from that law firm. These documents later became publicly available.

Q: Earlier you described the Merrill Williams documents. During the FDA investigation of the cigarette industry while you were FDA Commissioner, did the FDA examine the documents from the collection associated with Merrill Williams?

A: Yes.

Q: Did you review these documents in your capacity as FDA Commissioner?

A: Yes.

Q: Please direct your attention to U.S. Exhibits 20,995; 21,004; 21,008; 21,040; 21,772;

http://legacy.library.ucsf.edu/tid/qzq07a00/pdf
Digitized by the Industry Documents Library
http://www.industrydocuments.ucsf.edu/docs/hqhl0001

30,481; 31,031; 47,753; 52,685; 52,686; 54,049; 54,050; 54,051; and 54,052. Does this set of exhibits contain documents from the Merrill Williams collection?

A: I believe the answer is yes.

Q: Please describe this set of exhibits for the Court.

A: These documents include a proposal for the development of a public relations campaign to counter the risks associated with cigarettes. The document states: "Doubt is our product. It is the best means for competing with the 'body of fact' that exists in the mind of the general public. It is also the means of establishing a controversy."

These documents also reflect cigarette lawyers' views of the value of the Council for Tobacco Research "doing work in a non-directed and independent fashion," rather than doing it in-house, "which, if it goes wrong, can become the smoking pistol in a lawsuit."

Q: You testified earlier that, during the investigation of the cigarette industry the FDA conducted while you were Commissioner, you reviewed documents from the Merrill Williams collection and other various collections on the activities of the Tobacco Industry Research Council, the Council for Tobacco Research, and other related cigarette industry entities relating to these issues. How, if at all did your review of these documents inform the FDA investigation of the cigarette industry?

A: FDA's Findings that cigarette manufacturers understand that nicotine has addictive and other pharmacological effects, and that the industry has conducted extensive research and product development on nicotine delivery, were supported by some of these documents.

Q: As FDA Commissioner, what significance, if any, did the John Hill archives at the Wisconsin Historical Society, the Merrill Williams documents and the other various collections on the activities of Hill & Knowlton, the Tobacco Industry Research Council, the Council for Tobacco Research, and other related cigarette industry entities have relating to the issues investigated by the FDA investigation of the cigarette industry?

A: There were parallels between how the industry dealt with the smoking and cancer issues

http://legacy.library.ucsf.edu/tid/qzq07a00/pdf
Generated by http://www.industrydocuments.ucsf.edu/docs/hqhl0001

and how they dealt with the nicotine and addiction issues.

Q: What, if anything, did you come to understand during the FDA review of these documents relating to the extent, if any, to which the cigarette industry's actions in the area of smoking and disease were consistent with the actions of the cigarette industry on the issue of nicotine addiction?

A: What I came to understand by reading the industry documents was that the industry had developed a carefully constructed position, first to deny that cigarettes were proven to cause cancer and, later, to deny that nicotine in cigarettes was addictive.

Q: Explain how, if at all, the historical actions of the members of the cigarette industry who are defendants in this case on the issue of smoking and disease informed the FDA's understanding of the cigarette industry's conduct relating to the addictiveness of nicotine in cigarettes?

A: Just as the industry denied that the link between smoking and cancer had been proven, it also stated that there was no scientific proof that nicotine is an addictive substance.

Q: Now I would like to discuss the FDA Rulemaking process and the assertion of jurisdiction over cigarettes. What was the first step the FDA took toward asserting jurisdiction over cigarettes?

A: On August 11, 1995, we published in the Federal Register a Proposed Rule and analysis regarding agency-related jurisdiction. The agency sought public comment on these matters.

Q: How long did the investigation take from its beginning until the filing of the Proposed Rule and Jurisdictional Document?

A: Approximately a year and a half, although as I mentioned earlier preliminary work had been on-going for several years before the full investigation began.

Q: Who had access to these documents after they were filed?

A: Any member of the public who had access to the Federal Register.

Q: Earlier you testified about U.S. Exhibit 33,034, the FDA Proposed Rule and

http://legacy.library.ucsf.edu/tid/qzq07a00/pdf Document hosted at industrydocuments.ucsf.edu/docs/hqhl0001

Jurisdictional Document, with Appendices. Please describe the Proposed Rule and the corresponding Jurisdictional Document for the Court.

A: It is over 650 pages in length. The Jurisdictional Document has three parts. Part one was the legal analysis of tobacco products. Part two consisted of the Agency's findings. This part consisted of two main sections. The first presented scientific evidence of nicotine's addictive and other pharmacological effects, how cigarettes deliver pharmacologically active doses of nicotine and how consumers use these products for drug effects. The second section of the agency's findings detail the statements, extensive research and action by the tobacco manufacturers regarding nicotine's pharmacological effects. The third part discussed FDA's regulatory action and documented that, since a ban on cigarettes would not be feasible and since virtually all tobacco use begins in childhood and adolescence, the goal of FDA's regulation was to reduce tobacco in children and teenagers and to prevent future generations from becoming addicted. The proposed rule provided documentation and proposed regulations that would reduce children's and adolescents' access to tobacco products, as well as to decrease the amount of positive imagery that makes these products so appealing to young people, and to reduce the appeal created by decades of pro-tobacco messages.

Q: After the FDA filed the FDA Jurisdictional Document and the related FDA Proposed Rule, what was the next part of the process through which the FDA asserted jurisdiction over cigarettes?

A: It sought public comment, analyzed those comments and prepared and published a Final Rule and Jurisdictional Determination, which included responses to the comment submitted to the agency.

Q: When did the FDA file the Final Rule and Jurisdictional Determination?

A: August 28, 1996.

Q: Turn your attention to U.S. Exhibit 64,323. What is this exhibit?

A: This is a compilation of the FDA Final Rule and Jurisdictional Determination.

http://legacy.library.ucsf.edu/tid/qzq07a00/pdf Document hosted at industrydocuments.ucsf.edu/docs/hqhl0001

Q: Describe the FDA Final Rule and corresponding Jurisdictional Determination for the Court.

A: It is over 800 pages in length, it sets out the final regulations, the agency's findings on jurisdiction and a detailed response the comments submitted on both jurisdictional and proposed regulation. It was published in the Federal Register.

Q: Describe the volume of the comments provided in response to the Proposed Rule and the corresponding jurisdictional documents.

A: It was extensive. We took over a warehouse to be able to handle all the comments.

Q: Did the comments to these FDA filings include industry documents submitted by some of the defendants in this litigation?

A: Yes, the tobacco companies who are defendants in this case submitted volumes of comments. The Tobacco Institute submitted joint industry comments. Individual companies also submitted comments.

Q: And did the FDA ever reopen the comment period?

A: Yes; my recollection is that certain additional evidence came in during the comment period and the agency wanted to permit public comment on that evidence also so it extended comment period.

Q: Now I would like to turn to the general conclusions of the FDA Final Rule and Jurisdictional Determination. Please turn to U.S. Exhibit 64,323, the Final Rule with Jurisdictional Determination, at Federal Register page 44,629. What FDA conclusion, if any, is reflected – in the last paragraph – on the issue of whether cigarettes are nicotine delivery devices under the Federal Food, Drug and Cosmetic Act?

A: The FDA concluded that cigarettes and smokeless tobacco "meet the statutory definition of a drug and a device." FDA reached this conclusion "based on two determinations: (1) nicotine in cigarettes and smokeless tobacco does 'affect the structure or any function of the body,' and (2) these effects on the structure and function of the body are 'intended' by the manufacturers."

http://legacy.library.ucsf.edu/tid/qzq07a00/pdf
Digitized by the Legacy Industry Documents Library. http://www.industrydocuments.ucsf.edu/docs/hqhl0001

Q: What bases are identified, if any, for this conclusion?

A: The Agency's Jurisdictional Document contained over 1,250 footnotes that cited scientific reports, tobacco industry documents, and comments submitted to the Agency, among other documents. That documentary evidence provided the basis for FDA's conclusions.

Q: Dr. Kessler, I would now like to discuss several documents that the Court may find informative on the issue of addiction. Please turn your attention to U.S. Exhibit 20,659. What is this exhibit?

A: This is an R.J. Reynolds document signed by Claude E. Teague, Jr.–who was Assistant Director of R&D Services at R.J. Reynolds when he wrote this document, and who later became Director of Research Services-on April 14, 1972, titled "Research Planning Memorandum on the Nature of the Tobacco Business and the Crucial Role of Nicotine Therein."

Q: Describe the actions, if any, that you took as Commissioner of the Food and Drug Administration upon reading U.S. Exhibit 20,659?

A: I asked the Tobacco Team to meet me at my house the next morning, and we gathered in the living room. Mr. Zeller read portions of the document out loud.

Q: Is U.S. Exhibit 20,659 cited in the FDA Final Jurisdictional Document relating to cigarettes?

A: Yes. There are several pages of analysis about this memorandum.

Q: Please turn to Bates page 500915684 of U.S. Exhibit 20,659. Describe for the Court the statements of Dr. Teague of R.J. Reynolds on the first paragraph of this page.

A: The memorandum describes the tobacco industry as being "a specialized, highly ritualized and stylized segment of the pharmaceutical industry." The memorandum went on to say that "tobacco products, uniquely, contain and deliver nicotine, a potent drug with a variety of physiological effects." Dr. Teague noted that nicotine is a "habit-forming alkaloid" and that the "confirmed user" smokes "for the physiological 'satisfaction' derived from nicotine." Dr.

http://legacy.library.ucsf.edu/tid/qzq07a00/pdf Document hosted at industrydocuments.ucsf.edu/docs/hqhl0001

Teague stated that the tobacco industry is "based upon design, manufacture and sale of attractive dosage form of nicotine . . ."

The Teague memorandum describes cigarettes as drug delivery devices. According to Dr. Teague of R.J. Reynolds, a tobacco product is "in essence, a vehicle for delivery of nicotine."

Q: Of what import, if any, were these statements by Dr. Teague, as Assistant Director of Research Services at R.J. Reynolds, to the FDA investigation?

A: The statements, among others, demonstrated that key industry officials knew nicotine was a drug and said it long before FDA did.

Q: Dr. Kessler, please direct your attention to U.S. Exhibits 20,950; 22,034; 22,967; 26,080; 47,530; 85,279; 85,281; 85,828; and 88,066. How many of these documents, if any, are cited in the FDA Final Rule?

A: Each and every one of them.

Q: Describe the significance of these documents, if any, to the FDA's examination of the defendants' understanding of the reasons people smoke.

A: These documents demonstrate the following: (1) that the cigarette industry understood that people smoke primarily for nicotine; (2) that the industry knew that people smoke for the drug effects of nicotine; (3) that the cigarette manufacturers recognized that cigarettes were drug delivery devices.

Q: Dr. Kessler, please direct your attention to U.S. Exhibits 20,246; 21,562; 47,776; 53,468; and 85,420, as well as U.S. Exhibit 22,034, which we just discussed. How many of these exhibits, if any, are cited in the FDA Final Rule?

A: Each and every one of these.

Q: Describe the significance of these documents, if any, to the FDA's understanding of whether the members of the cigarette industry who are defendants in this case considered nicotine addictive.

A: They demonstrate that, dating back now more than four decades, industry officials

http://legacy.library.ucsf.edu/tid/qzq07a00/pdf
Digitized by http://www.industrydocuments.ucsf.edu/docs/hqhl0001

understood that nicotine is addictive, and as stated by Addison Yeaman, a high-ranking Brown & Williamson official, in 1963, "we are, then, in the business of selling nicotine, an addictive drug."

Q: Dr. Kessler, please review U.S. Exhibits 20,592; 48,076; 53,430; 54,206; and 87,122. How many of these exhibits, if any, are cited in the FDA Final Rule?

A: Each and every one.

Q: Describe how, if at all, these exhibits relate to conduct of the members of the cigarette industry who are defendants in this case relating to drug effects of nicotine.

A: The documents demonstrate that the industry was focused on the drug effects of nicotine, including the mechanisms of how nicotine interacted with the central nervous system (brain) and other organs. Human studies were undertaken to understand the pharmacokinetics (the action of drugs in the body including how it is absorbed, metabolized, distributed to tissues, duration of action, and elimination from the body) of nicotine. Attention was also paid to the "desired effects of brain stimulation."

Q: What, if anything, does the FDA Rule–U.S. Exhibit 64,323–state on this topic at Federal Register pages 44,915 and 44,950?

A: The FDA stated that, based on the statements, research, and actions of the cigarette manufacturers, it concluded that "The Cigarette Manufacturers Have Conducted Extensive Product Research and Development To Optimize the Delivery of Nicotine" and that "The Cigarette Manufacturers Design Commercially Marketed Cigarettes to Provide a Pharmacologically Active Dose of Nicotine."

Q: Do these subject headings themselves reflect conclusions of the Food and Drug Administration?

A: Yes.

Q: Dr. Kessler, I would now like to review for the Court some of the evidence the FDA relied upon in support of its conclusion that the cigarette manufacturers manipulate the

http://legacy.library.ucsf.edu/tid/qzq07a00/pdf
Digitized by http://www.industrydocuments.ucsf.edu/docs/hqhl0001

nicotine in the cigarettes they sell. Please turn to Federal Register page 44,640. What, if any, FDA conclusions relating to low tar cigarettes are reflected on this page?

A: The FDA stated "the evidence in the record shows that the manufacturers conducted extensive product research and development to find ways to maintain adequate nicotine levels in low tar cigarettes."

Q: Dr. Kessler, please review U.S. Exhibits 21,507 and 85,449. Did you review both these documents in your official capacity as FDA Commissioner during the FDA investigation of the cigarette industry?

A: Yes.

Q: Does the FDA include citations to both these documents in the FDA Jurisdictional Document accompanying the FDA Final Rule?

A: Yes.

Q: Please describe for the Court the significance, if any, of these documents to the FDA investigation, insofar as it related to low tar cigarettes.

A: Both documents demonstrate that British American Tobacco Company and Brown & Williamson Tobacco Company understood that "nicotine is both the driving force and the signal (as impact) for compensation in human smoking behaviour." U.S. Exhibit 85,449 describes compensation as the ability for a smoker "to obtain delivery of smoke greater than that recorded" in the published numbers. The companies' product research and development work focused on maintaining nicotine deliveries for light cigarettes. U.S. Exhibit 21,507 supports the notion of compensation by stating "whatever the characteristics of cigarettes as determined by smoking machines, the smoker adjusts his pattern to deliver his own nicotine requirements (about 0.8 mg. per cigarette)." U.S. Exhibit 85,449 shows that a focus of the companies' research and development was on "designing products which aid smoker compensation." One of the methods discussed is to change the "elasticity" of the cigarette by product design. "Elasticity," according to the document, refers to the ability of a cigarette to permit a smoker to compensate and achieve

http://legacy.library.ucsf.edu/tid/qzq07a00/pdf Document hosted at industrydocuments.ucsf.edu/docs/hqhl0001

the nicotine the smoker needs. According to U.S. Exhibit 85,449, the consensus at British American Tobacco was that "small improvements in elasticity, which are less obvious, visually or otherwise, are likely to be an acceptable route." These documents provide evidence of an effort to try and manipulate nicotine deliveries to assure that smokers receive an adequate dose of nicotine.

Q: Please direct your attention to two documents that the Court may find informative relating to nicotine manipulation, U.S. Exhibits 85,422 and 85,492. Did you review these documents in your official capacity at the FDA?

A: Yes.

Q: Did the FDA cite these documents in the FDA Final Rule?

A: Yes.

Q: How, if at all, did the Food and Drug Administration consider these documents significant to the conclusions of the FDA as regards nicotine manipulation?

A: U.S. Exhibit 85,422 demonstrates that research at Philip Morris had as its goal "to determine optimal nicotine/tar ratios for cigarette acceptability of relatively low delivery cigarettes." This and other documents in the administrative record indicated that, for decades, the cigarette manufacturers sought to develop ways to maintain adequate doses of nicotine in low-yield cigarettes, and that a major focus of cigarette manufacturers was to deliver adequate doses of nicotine to consumers. Altering the nicotine/tar ratio was one way the industry sought to accomplish this. U.S. Exhibit 85,492 documents other research aimed at increasing and optimizing nicotine deliveries. This document, written in 1974, discussed two ways to manipulate the nicotine content in what the industry called "reconstituted tobacco," which is a manufactured sheet made of various tobacco materials and waste utilized in many cigarettes. One potential method was to add nicotine in a concentrated extract; another method was to change to blend formulas that utilized higher nicotine tobaccos in the reconstituted sheet. This and other documents demonstrated that the industry was focused on researching ways to

http://legacy.library.ucsf.edu/tid/qzq07a00/pdf Document hosted at industrydocuments.ucsf.edu/docs/hqhl0001

manipulate nicotine levels in tobacco.

Q: Do Federal Register pages 45,239, 45,243 and 45,247 of U.S. Exhibit 64,323 contain conclusions that the FDA reached relating to youth smoking?

A: Yes.

Q: Please convey these conclusions to the Court.

A: First, that "new information shows that cigarette and smokeless tobacco use begins almost exclusively in childhood and adolescence." Second, that "new information shows that effective restrictions on access and advertising to children and adolescents can decrease tobacco use by children." Third, "that new information indicates that regulatory interventions can reduce tobacco-related illnesses if they focus on preventing children from becoming addicted."

Q: Turn your attention to U.S. Exhibits 64,593 and 33,038. Are these exhibits cited in the FDA Final Rule?

A: Yes.

Q: Describe these documents and explain to the Court what relationship they have, if any, to the conclusions reached by the FDA relating to youth smoking.

A: One document is the 1994 Report of the Surgeon General. The second document is a 1994 report by the Institute of Medicine on preventing nicotine addiction by children and youth. These documents provided data and analyses that revealed that the vast majority of tobacco users begin their use while children or adolescents. These documents also demonstrated that the industry's advertising and promotion of cigarettes is attractive to young people and influences these children and adolescents to use cigarettes.

Q: Directing your attention to U.S. Exhibits 20,708; 20,711; 21,605; and 20,938, are these documents cited in the FDA Proposed Rule, in the Final Rule or in the related jurisdictional documents?

A: Yes.

Q: How, if at all, did U.S. Exhibits 20,708; 20,711; 21,605; and 20,938 relate to the

http://legacy.library.ucsf.edu/tid/qzq07a00/pdf Document hqhl0001 industrydocuments.ucsf.edu/docs/hqhl0001

conclusions the FDA reached relating to youth smoking during your service as FDA Commissioner?

A: Ten years ago, I read the marketing research study prepared for Brown & Williamson's affiliate. U.S. Exhibit 20,938 is titled "Project Plus/Minus," and it references an earlier marketing research study that I also read, called "Project Sixteen." There is a phrase in this report that struck me then as key to my understanding that nicotine addiction begins as a pediatric disease–"but addicted they do indeed become . . ."

Even as a pediatrician, I did not realize that teenagers were becoming addicted until I read these marketing studies. These documents made me realize that nicotine addiction begins as a pediatric disease.

Q: What, if any, challenges were made to the FDA authority to regulate tobacco?

A: The cigarette manufacturers and the Tobacco Institute filed suit against the Food and Drug Administration in United States District Court in Greensboro, North Carolina. They challenged the FDA's authority to regulate tobacco.

Q: Describe the nature and extent of the appeals, if any, resulting from this lawsuit.

A: The Supreme Court granted certiorari to hear the case.

Q: What was the holding of the U.S. Supreme Court on the issue of whether the FDA had jurisdiction to regulate tobacco products?

A: The Supreme Court held that Congress did not intend to give FDA authority to regulate cigarettes.

Q: Did any of the Justices involved in the ruling take issue with any of the factual findings in the FDA investigation?

A: No.

Q: Did any of the Justices involved in the ruling dispute any of the factual conclusions, or the evidence supporting them, in the Proposed Rule, Final Rule or the corresponding jurisdictional documents?

http://legacy.library.ucsf.edu/tid/qzq07a00/pdf
Document hosted at industrydocuments.ucsf.edu/docs/hqhl0001

A: No.

Q: Given the final outcome by the U.S. Supreme Court, of what value, if any, are FDA's findings?

A: FDA's findings demonstrate what the cigarette industry knew and how it acted over decades.

Q: Please review U.S. Exhibit 88,196. What is this exhibit?

A: It is a document that is stamped from the State Historical Society of Wisconsin, Archives Division, and is titled "A Frank Statement to Cigarette Smokers." It is signed by the Tobacco Industry Research Committee and sponsored by Philip Morris, R.J. Reynolds, Lorillard, American Tobacco, Benson & Hedges, Brown & Williamson and other companies.

Q: Did you review this document in your official capacity as FDA Commissioner during the FDA investigation of the cigarette industry?

A: Yes.

Q: What is stated in the last sentence in the left column of this document?

A: "We always have and always will cooperate closely with those whose task it is to safeguard the public health."

Q: Was it the task of the FDA to safeguard the public health during the time you served as FDA Commissioner?

A: Yes.

Q: In your experience as FDA Commissioner, to what extent, if any, did the members of the cigarette industry who are defendants in this case "cooperate closely" with the FDA during the FDA investigation of the cigarette industry?

A: Based on my experience, cigarette manufacturers and the Tobacco Institute did the opposite. Parts of the industry waged, I think is fair to say, a significant attack on the Agency. At the very least, I think it is fair to say that some in the industry, at times, were not forthcoming with the Agency. Beyond that, there were times, through the course of our investigation, where

http://legacy.library.ucsf.edu/tid/qzq07a00/pdf
Digitized by http://www.industrydocuments.ucsf.edu/docs/hqhl0001

we felt that we were misled by statements of cigarette company officials about significant issues that we were investigating.

http://legacy.library.ucsf.edu/tid/qzq07a00/pdf
Digitized by the Industry Documents Library
http://www.industrydocuments.ucsf.edu/docs/hqhl0001